PJF/BZS/ 706002-0039 #41529

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

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

PATRICK MCCARTHY, M.D.'S ANSWER TO PLAINTIFF'S THIRD AMENDED COMPLAINT AT LAW

NOW COMES the Defendant, **PATRICK MCCARTHY, M.D.,** by and through his attorneys, **ANDERSON, RASOR & PARTNERS, LLP,** in Answering Plaintiff's Final Third Amended Complaint at Law, states as follows:

GENERAL ALLEGATIONS:
Background – Plaintiff's Cardiac Condition, Care and Surgery of November 6, 2006

1. The Plaintiff, Maureen Obermeier, was born on August 12, 1956 and in November of 2006 was 50 years of age. Prior to November 6, 2006, Plaintiff suffered from a longstanding heart condition commonly known as mitral valve prolapse. Plaintiff developed mitral regurgitation. For a period of years prior to November of 2006, Plaintiff had been treated by a cardiologist, Dr. Paul Silverman, who was on staff at Advocate Christ Hospital in Oak Lawn, Illinois. During approximately the one year prior to November of 2006, Plaintiff began experiencing increasing fatigue, indicating that her mitral valve condition was worsening. As of November 2006, Plaintiff had no other significant heart disease, including no underlying coronary artery disease, and had no other significant heart impairment.

ANSWER: **This defendant admits only the following: the Plaintiff, Maureen Obermeier, was born on August 12, 1956 and in November of 2006 was 50 years of age; Prior to November 6, 2006, Plaintiff suffered from a longstanding heart condition commonly known as mitral valve prolapse; Plaintiff developed mitral regurgitation; For a period of years prior**

to November of 2006, Plaintiff had been treated by a cardiologist, Dr. Paul Silverman, who was on staff at Advocate Christ Hospital in Oak Lawn, Illinois. Plaintiff's mitral valve condition was worsening as of November 2006; this Defendant denies the remaining allegations of Paragraph 1 of Plaintiff's General Allegations to the extent that they exceed or are inconsistent with the foregoing.

2. The cardiac surgery staff at Christ Hospital recommended that Plaintiff undergo a mitral valve replacement with a mechanical valve. This procedure would have required Plaintiff to take blood thinner medications for the remainder of her life. Plaintiff opted to seek out a second opinion to determine if any other medical options were available.

ANSWER: This defendant admits only the following: the cardiac surgery staff at Christ Hospital recommended that Plaintiff undergo a mitral valve replacement with a mechanical valve; this procedure would have required Plaintiff to take blood thinner medications for the remainder of her life; Plaintiff opted to seek out a second opinion to determine if any other medical options were available; this Defendant denies the remaining allegations of Paragraph 2 of Plaintiff's General Allegations to the extent that they exceed or are inconsistent with the foregoing.

3. On or about September 21, 2006, Plaintiff sought and received a second opinion for the treatment of her condition from Patrick McCarthy, MD ("Dr. McCarthy") of Northwestern Memorial Hospital ("NMH"). During this visit, Dr. McCarthy reviewed Plaintiff's medical history, evaluated her condition, and diagnosed Plaintiff as suffering from myxomatous disease. Dr. McCarthy recommended a surgical *repair* of the mitral valve, rather than mitral valve *replacement*. Dr. McCarthy explained that certain risks were associated with a valve repair which he described as having a less than 1% mortality risk. Plaintiff agreed to proceed with the mitral valve repair procedure proposed by Dr. McCarthy.

ANSWER: This Defendant admits only the following: on or about September 21, 2006, Plaintiff sought and received a second opinion for the treatment of her condition from Patrick McCarthy, MD ("Dr. McCarthy") of Northwestern Memorial Hospital ("NMH"); during this

visit, Dr. McCarthy reviewed Plaintiff's medical history, evaluated her condition, and diagnosed Plaintiff as suffering from myxomatous disease; Dr. McCarthy recommended a surgical *repair* of the mitral valve, rather than mitral valve *replacement*; Plaintiff agreed to proceed with the mitral valve repair procedure proposed by Dr. McCarthy. This Defendant denies the remaining allegations of Paragraph 3 of Plaintiff's General Allegations to the extent that they exceed or are inconsistent with the foregoing.

4. On or about October 10, 2006, Plaintiff came to NMH and met with members of Dr. McCarthy's medical team. During this meeting, Plaintiff reviewed, approved and signed several consent forms relating to the surgery.

ANSWER: **This Defendant denies the allegations in paragraph 4.**

5. On November 6, 2006, Plaintiff presented to NMH and underwent the mitral valve repair surgery. Dr. McCarthy performed the surgery. He was assisted by his NMH surgical team, which comprised an anesthesiologist, perfusionist, and various resident physicians, fellows, nurses, and others.

ANSWER: **This Defendant admits only that on November 6, 2006, Plaintiff presented to NMH and underwent the mitral valve repair surgery. Dr. McCarthy performed the surgery. This Defendant denies the remaining allegations of Paragraph 5 of Plaintiff's General Allegations to the extent that they exceed or are inconsistent with the foregoing.**

6. During the repair, Dr. McCarthy implanted into Plaintiff's mitral valve a 36mm annuloplasty ring, then known as the "Myxo Ring" and also as the "McCarthy annuloplasty ring" or the "Model 5100 annuloplasty ring" (hereinafter the "Myxo Ring"). The ring implanted into Plaintiff bore serial number 567372, and was manufactured, distributed and sold into commerce by Defendant, Edwards Lifesciences, LLC.

ANSWER: **This Defendant admits only that certain medical records indicate that during the repair, Dr. McCarthy implanted into Plaintiff's mitral valve a 36mm annuloplasty ring, then known as the "Myxo Ring". The ring that was implanted in the Plaintiff bore serial number 567372. This Defendant makes no answer to the allegations pertaining to Edwards,**

and denies that it obligated to do so, as they are not directed at this Defendant. This Defendant denies the remaining allegations of Paragraph 6 of Plaintiff's General Allegations to the extent that they exceed or are inconsistent with the foregoing.

7. During the November 6, 2006 surgery, while Plaintiff was still in the operating room, one of Plaintiff's coronary arteries was injured and became obstructed, causing a myocardial infarction, *i.e.*, a heart attack. While in the operating room, Plaintiff suffered ventricular fibrillation ("Vfib"), for which she was cardioverted four times. Plaintiff was then transferred to the hospital's surgical intensive care unit, where she experienced a second episode of Vfib, and was again cardioverted. The Plaintiff's heart attack severely and permanently damaged Plaintiff's left ventricle and substantially reduced the functioning of her heart, and has caused other severe and permanent cardiac related medical complications.

ANSWER: **This Defendant admits only the following: while in the operating room, Plaintiff suffered ventricular fibrillation ("Vfib"), for which she was cardioverted four times; Plaintiff was then transferred to the hospital's surgical intensive care unit, where she experienced a second episode of Vfib, and was again cardioverted. This Defendant denies the remaining allegations of Paragraph 7 of Plaintiff's General Allegations to the extent that they exceed or are inconsistent with the foregoing.**

8. On November 6, 2006, while in the intensive care unit, Plaintiff underwent an electrocardiogram (ECG) at approximately 1:13 p.m., which was less than one hour after her surgery ended. The ECG demonstrated that Plaintiff suffered a heart attack.

ANSWER: **This Defendant admits only that on November 6, 2006, while in the intensive care unit, Plaintiff underwent an electrocardiogram (ECG) at approximately 1:13 p.m., which was less than one hour after her surgery ended. The ECG demonstrated that Plaintiff suffered a heart attack. This Defendant denies the remaining allegations of Paragraph 8 of Plaintiff's General Allegations to the extent that they exceed or are inconsistent with the foregoing.**

9. The Plaintiff remained an inpatient at NMH from November 6, 2006 through November 12, 2006. During her hospital stay, Plaintiff's heart functioning, particularly the heart's pumping capacity, was substantially diminished. Several follow-up tests and studies were performed which showed that Plaintiff suffered severe damage to the posterior and lateral walls of her left ventricle. The Plaintiff's ejection fraction, which measures the pumping capacity of her left ventricle, fell into the range of 30 to 35, which represents a substantial reduction.

ANSWER: **This Defendant admits only that the Plaintiff remained an inpatient at NMH from November 6, 2006, through November 12, 2006. This Defendant denies the remaining allegations of Paragraph 9 of Plaintiff's General Allegations to the extent that they exceed or are inconsistent with the foregoing.**

10. Following her discharge from NMH, Plaintiff followed-up with Dr. Paul Silverman, her long-standing cardiologist from Advocate Christ Hospital in Oak Lawn, Illinois.

ANSWER: **This Defendant admits only following her discharge from NMH, Plaintiff followed-up with Dr. Paul Silverman, her long-standing cardiologist from Advocate Christ Hospital in Oak Lawn, Illinois. This Defendant denies the remaining allegations of Paragraph 10 of Plaintiff's General Allegations to the extent that they exceed or are inconsistent with the foregoing.**

11. No one from NMH disclosed to Plaintiff that she had suffered a heart attack, or that her heart functioning had been permanently damaged. No one from NMH disclosed to Plaintiff's treating cardiologist, Dr. Paul Silverman, that his patient had suffered a heart attack, or that her heart wall was permanently damaged.

ANSWER: **This Defendant denies each and every allegation in Paragraph 11.**

12. While Plaintiff was receiving her follow-up care by Dr. Paul Silverman, she experienced continued cardiac related complications for which she has received a surgically implanted pacemaker and defibrillator, among other forms of continuing cardiac care.

ANSWER: **This Defendant denies each and every allegation in Paragraph 12.**

13. Plaintiff's claims include claims for medical negligence. The report and affidavit required pursuant to 735 ILCS 5/2-622 are attached as Exhibit A.

ANSWER: This Defendant admits only that an ostensible 2-622 report and affidavit is attached but denies the sufficiency of said report and affidavit.

14. The Plaintiff did not know, nor could she have reasonably known, of her injury or that it was wrongfully caused until, at the earliest, October of 2008. The above-described post-surgical ECG of November 6, 2006, which demonstrated Plaintiff's myocardial infarction, was not produced to the Plaintiff until after this lawsuit was filed.

ANSWER: This Defendant denies each and every allegation in Paragraph 14.

The Northwestern Parties

15. At all relevant times herein, Northwestern Memorial Hospital was and is now a corporation duly authorized and existing under Illinois law which owned, operated and maintained a certain hospital in Chicago, Illinois.

ANSWER: This Defendant makes no answer to Paragraph 15 and denies that he is obligated to do so, as it is not directed at this Defendant.

16. At all relevant times herein, The Northwestern Memorial Faculty Foundation ("NWMFF") was and is now a corporation duly authorized under Illinois law which employed various physicians.

ANSWER: This Defendant makes no answer to Paragraph 16 and denies that he is obligated to do so, as it is not directed at this Defendant.

17. At all relevant times herein, Dr. McCarthy was a physician duly licensed to practice medicine in Illinois and who specialized in cardiothoracic surgery.

ANSWER: This Defendant admits the allegations in Paragraph 17.

18. At all times relevant, Dr. McCarthy was and is now employed by and the agent of The Northwestern Memorial Faculty Foundation and all acts and/or omissions on Dr. McCarthy's part as alleged herein were in the course and scope of his employment thereby.

ANSWER: This Defendant admits the allegations in Paragraph 18.

19. At all relevant times herein, Dr. McCarthy was and now is licensed and has held privileges to practice medicine, perform cardiac surgery, and see patients at NMH and is and has been the actual, implied or apparent agent of Northwestern Memorial Hospital, and all acts and/or

omissions by Dr. McCarthy as alleged herein were also in the course and scope of this agency.

ANSWER: This Defendant admits only that he held privileges at NMH and is licensed and has held privileges to practice medicine, perform cardiac surgery, and see patients but denies the remaining allegations in Paragraph 19.

20. Also, at all times relevant herein, Dr. McCarthy has been and is employed by Northwestern University as a Professor of Medicine, and is and has been subject to the University's mandates, policies, regulations and norms governing the medical services he provides.

ANSWER: This Defendant admits only that he was a Professor of Medicine at the Feinberg School of Medicine. This Defendant denies the remaining allegations of Paragraph 20 of Plaintiff's General Allegations to the extent that they exceed or are inconsistent with the foregoing.

Edwards and the Myxo Ring

21. At all relevant times, Edwards Lifesciences, LLC ("Edwards") has been and is a corporation duly authorized to do business in Illinois. Edwards is in the business of designing, manufacturing, marketing, selling into commerce and distributing medical devices.

ANSWER: This Defendant makes no answer to Paragraph 21, and denies that he is obligated to do so, as it is not directed at this defendant.

22. At all relevant times, Edwards manufactured, marketed and distributed a cardiac medical device commonly known as an annuloplasty ring, to which it assigned Model No. 5100. The device has had different trade names assigned to it by Edwards over time, including, (a) the "McCarthy annuloplasty ring," (b) the "Myxo ETlogix annuloplasty ring," and much later (c) the "ETlogix annuloplasty ring" Plaintiff hereinafter refers to this medical device as the "Myxo Ring."

ANSWER: This Defendant makes no answer to Paragraph 22, and denies that he is obligated to do so, as it is not directed to this Defendant.

23. Dr. McCarthy invented the Myxo Ring. On April 29, 2004, Dr. McCarthy and Edwards applied to the United States Patent Office for a patent on the Myxo Ring. The patent was issued on November 13, 2007, bearing patent No. 7,294,148. As of November 2006, the Myxo Ring

was "patent pending." Dr. McCarthy and Edwards thus own the patent rights in and the right to royalties on sales of the Myxo Ring.

ANSWER: This Defendant admits only that he invented the Myxo ring and that he applied for a patent for the ring. This Defendant lacks sufficient knowledge and information to either confirm or deny the remaining allegations of Paragraph 23.

24. As part of the patent application process, Edwards and Dr. McCarthy claimed to the United States Patent Office that the Myxo Ring was unique to other pre-existing annuloplasty rings in more than forty respects, including its triangular shape, a curved three-dimensional composition, a significant silicone content, and the required use of unique calipers to facilitate a variation in surgical techniques.

ANSWER: This Defendant lacks sufficient knowledge and information to either confirm or deny the remaining allegations in Paragraph 24.

25. Edwards and Dr. McCarthy have otherwise represented that the Myxo Ring was uniquely designed and intended for the treatment of myxomatous disease.

ANSWER: This Defendant denies each and every allegation in Paragraph 25.

26. At all relevant times, Dr. McCarthy has been and is a paid consultant for Edwards in which Dr. McCarthy provides consulting services to Edwards on such matters including the safety and efficacy of the Myxo Ring, and Dr. McCarthy has been and is an actual, apparent, or implied agent of Edwards. All acts and/or omissions alleged herein by Dr. McCarthy were in the course and scope of this agency.

ANSWER: This Defendant admits only that he provided consulting services to Edwards. This Defendant denies the remaining allegations in Paragraph 26.

27. As of November 2006, the Myxo Ring was made available and was used solely at Northwestern Memorial Hospital by Dr. McCarthy and one of his colleagues. The Myxo Ring did not become commercially available until some time after January 2007.

ANSWER: This Defendant denies each and every allegation in Paragraph 27.

28. In and around October 2008, Edwards suspended new sales and deliveries of the Myxo Ring and recalled the Myxo Rings which were then in the American marketplace.

ANSWER: This Defendant lacks sufficient knowledge and information to either confirm or deny the remaining allegations in Paragraph 28.

COUNT I – PRODUCT LIABILITY – STRICT LIABILITY

This Defendant makes no answer to Count I, and denies that he is obligated to do so, as it is not directed at this Defendant.

COUNT II – PRODUCT LIABILITY – NEGLIGENCE
Marketing, Sale and Distribution
Edwards Lifesciences, LLC Only

This Defendant makes no answer to Count II, and denies that he is obligated to do so, as it is not directed at this Defendant.

COUNT III – PRODUCT LIABILITY – NEGLIGENCE
Failure to Warn or Instruct
Edwards Lifesciences, LLC Only

This Defendant makes no answer to Count III, and denies that he is obligated to do so, as it is not directed at this Defendant.

COUNT IV – RES IPSA LOQUITUR - Edwards Only
(Previously Dismissed as Count III – Replead solely to preserve the claim)

This Defendant makes no answer to Count IV, and denies that he is obligated to do so, as it is not directed at this Defendant.

COUNT V – STRICT LIABILITY – Dr. McCarthy Only as Agent of Edwards
(Previously Dismissed Claim – Replead solely to preserve the claim)

This Defendant makes no answer to Count V, and denies that he is obligated to do so, as it has been previously dismissed by this Court.

COUNT VI – INFORMED CONSENT
Northwestern Memorial Hospital Only – Direct Duty

This Defendant makes no answer to Count VI, and denies that he is obligated to do so, as it not directed at this Defendant, and it has been previously dismissed by this Court on August 16, 2010.

COUNT VII – INFORMED CONSENT
Patrick McCarthy, MD/NWMFF and Northwestern Memorial Hospital via Agency

1) Plaintiff realleges and reaffirms Paragraphs 1 through 28 of the General Allegations as and for this paragraph.

ANSWER: **This Defendant repeats and hereby incorporates by reference its answers to Paragraphs 1-28 of Plaintiff's Third Amended Complaint as his answers to Paragraph 1 of Count VII of Plaintiff's Third Amended Complaint as if fully set forth herein.**

2) In regard to the consent obtained from Plaintiff and at all relevant times relating thereto, Dr. McCarthy was employed by NWMFF and all acts and omissions on his part were in the course and scope of his employment thereby.

ANSWER: **This Defendant admits only that he was employed by Northwestern Medical Faculty Foundation and that he was acting within the scope of his employment during his care and treatment of the Plaintiff. This Defendant denies the remaining allegations of Paragraph 2 of Count VII to the extent that they exceed or are inconsistent with the foregoing.**

3) In regard to the consent obtained from Plaintiff and at all relevant times relating thereto, Dr. McCarthy was the apparent agent of Northwestern Memorial Hospital and all acts and omissions on his part were in the course and scope of his agency.

ANSWER: **This Defendant denies each and every allegation in Paragraph 3.**

4) In and prior to November of 2006, Northwestern University established and adopted policies and procedures involving medical research performed on human subjects, and involving the use of medical devices on human subjects. These policies and procedures applied to and were binding upon Dr. McCarthy, as a Professor of Medicine at Northwestern University.

ANSWER: This Defendant admits only that on and prior to November of 2006, Northwestern University established and adopted policies and procedures involving medical research performed on human subjects, and involving the use of medical devices on human subjects. This Defendant denies the remaining allegations in Paragraph 4.

5) In and prior to November of 2006, the above referenced Northwestern University policies and procedures also applied to and were binding upon Northwestern Memorial Hospital and its staff physicians, including Dr. McCarthy, in that the research and studies on human studies were performed at the hospital and the hospital provided the patients on whom the research was conducted.

ANSWER: This Defendant denies each and every allegation to Paragraph 5.

6) From March 15, 2006 through November 19, 2007, Dr. McCarthy performed a clinical study involving the Myxo Ring. Dr. McCarthy published the results of his study in the *Journal of Thoracic and Cardiovascular Surgery* on February 12, 2008. In it, Dr. McCarthy claimed that 124 patients were involved in the study, all of whom suffered myxomatous disease. He claimed to have implanted the Myxo Ring into 100 human subjects.

ANSWER: This Defendant denies each and every allegation in Paragraph 6.

7) During and prior to November of 2006, Dr. McCarthy and one other hospital colleague were the only surgeons in the world using the Myxo Ring. The device was not at the time commercially available.

ANSWER: This Defendant denies the allegations in Paragraph 7.

8) On September 21, 2006, Dr. McCarthy met with Plaintiff. Dr. McCarthy informed Plaintiff that she required surgery on her mitral valve. He informed Plaintiff that pre-operative studies showed that she suffered from myxomatous disease, but did not show the presence of rheumatic disease. Dr. McCarthy informed Plaintiff, among other things, that he would perform a repair of the valve using an annuloplasty ring unless, during the surgery, he found rheumatic disease. If rheumatic disease was present, Dr. McCarthy informed Plaintiff that she would require a mitral valve replacement rather than a repair.

ANSWER: This Defendant admits only that certain medical records reveal that this Defendant met with Plaintiff on September 21, 2006, and that he informed Plaintiff that she required surgery on her mitral valve. Further answering, this Defendant admits only that pre

operative studies showed that Plaintiff had myxomatous disease, but did not show the presence of rheumatic disease. This Defendant denies the remaining allegations of Paragraph 8 of Count VII to the extent that they exceed or are inconsistent with the foregoing.

9) On October 10, 2006, Plaintiff met with other members of Dr. McCarthy's team. Consent forms relating to her surgery were presented and signed. Neither Dr. McCarthy nor the other members of his team informed Plaintiff that Dr. McCarthy intended to implant a Myxo Ring into Plaintiff's mitral valve; the Myxo Ring was not cleared or approved by the FDA; the Myxo Ring was an investigational or experimental medical device; Dr. McCarthy was using and implanting the Myxo Ring into patients as part of a clinical study he was conducting on human patients; neither Northwestern University, its Institutional Review Board (IRB), nor the hospital had approved or authorized Dr. McCarthy's study; Dr. McCarthy invented, owned patent rights in, and received royalties on the Myxo Ring; or that Dr. McCarthy was using and implanting the Myxo Ring into patients in violation of numerous University policies and procedures, and in violation of federal regulations that governed the use of medical devices and the performance of clinical research on human subjects. Neither Dr. McCarthy nor the members of his team informed the Plaintiff that the Myxo Ring carried a risk of an obstruction to the coronary artery. Nor did Dr. McCarthy or any other member of his medical team inform Plaintiff that even though the Myxo Ring was contraindicated where rheumatic disease was present, Dr. McCarthy might nevertheless unilaterally opt to implant the device into a patient.

ANSWER: **This Defendant denies each and every allegation in Paragraph 9.**

10) On November 6, 2006, Dr. McCarthy performed open heart surgery upon Plaintiff. During the surgery he implanted a Myxo Ring into the Plaintiff's mitral valve. His operative report and other writings state that during the surgery, he found the presence of rheumatic disease. Dr. McCarthy nonetheless selected and implanted a Myxo Ring into Plaintiff's mitral valve.

ANSWER: **This Defendant admits On November 6, 2006, Dr. McCarthy performed open heart surgery upon Plaintiff. During the surgery he implanted a Myxo Ring into the Plaintiff's mitral valve. His operative report and other portions of the medical record state that during the surgery, he found the presence of rheumatic disease. Dr. McCarthy selected and implanted a Myxo Ring into Plaintiff's mitral valve. This Defendant denies the remaining allegations of Paragraph 10 of Count VII to the extent that they exceed or are inconsistent with the foregoing.**

11) Toward the end of the surgery and while still in the operating room, Plaintiff suffered a myocardial infarction, *i.e.*, a heart attack, and was cardioverted four times. The heart attack produced severe permanent damage to Plaintiff's left ventricle. Dr. McCarthy did not mention the Plaintiff's heart attack in his operative report. He never informed Plaintiff that she suffered a heart attack. His discharge summary failed to mention the heart attack and minimized the significance of the event by describing the Plaintiff's post-operative heart function as "mildly depressed" and "improved." Dr. McCarthy's published clinical study, described above, claimed that none of the patients receiving his Myxo Ring suffered peri-operative myocardial infarctions. On November 12, 2006, Plaintiff was discharged from Northwestern Memorial Hospital. Plaintiff left Dr. McCarthy's care without knowing and having no suspicion that she suffered a heart attack with severe permanent left ventricular damage while she was under Dr. McCarthy's care.

ANSWER: **This Defendant admits only that certain medical records reflect that the Plaintiff was cardioverted four times while in the operating room and that she suffered a heart attack. This Defendant denies the remaining allegations of Paragraph 11 of Count VII to the extent that they exceed or are inconsistent with the foregoing.**

12) At all relevant times, Defendants, Northwestern Memorial Hospital and NWMFF by and through their agent and employee, Dr. McCarthy, and Dr. McCarthy individually, were under a duty to inform the Plaintiff of those material risks, results and alternatives involving the surgery and to provide Plaintiff with material information involving the surgery which a reasonably well qualified cardiac surgeon would disclose under the same or similar circumstances.

ANSWER: **This Defendant admits only that he owed that duty imposed on him by law, if any, and denies any further allegations in Paragraph 12 of Count VII of Plaintiff's Third Amended Complaint to the extent they exceed or are inconsistent herewith.**

13) In violation of the above duty, defendants failed to disclose and inform the plaintiff of the following:

a) The Myxo Ring was not approved or cleared by the FDA;

b) The Myxo Ring, as of November 2006, was an investigational or experimental device or that it was not then even commercially available;

c) Dr. McCarthy was using the Myxo Ring on patients in November 2006 as part of a clinical study and research involving human subjects and that his use of the Myxo ring on

Plaintiff was or could be a part of the study;

d) The FDA was required to, but had not granted an IDE for use of the experimental Myxo Ring;

e) Approval of the Northwestern University IRB was required for use of the Myxo Ring, but that such approval had not been obtained;

f) Approval of the Northwestern University IRB was required for Dr. McCarthy's study of the Myxo Ring, but had not been obtained;

g) The purposes of Dr. McCarthy's Myxo Ring study, that it involved an experimental medical device, whether compensation was available for injuries, whether treatments were available for injuries, notice that participation in the study was voluntary, and the circumstances under which Dr. McCarthy could terminate her participation without the patient's consent;

h) Informed consent procedures and forms approved by Northwestern University's IRB were required for use of the Myxo Ring, but had not been obtained;

i) A specialized signed written consent form involving the Myxo Ring was required from the patient, but would not be obtained;

j) Dr. McCarthy owned the patent on the Myxo Ring; he receives royalties on the sale and use of the Myxo Ring, and he had a financial interest in the outcome of his clinical study and its results;

k) The Myxo Ring was being used by Dr. McCarthy prior to the time that any safety protocols had been put into place, including protocols adopted by the hospital, the university, and by industry and medical standards;

l) The IRB and Northwestern Memorial Hospital had not analyzed or determined the appropriateness of Dr. McCarthy's research study involving the use of the Myxo Ring on human subjects;

m) In November 2006, there was no or insufficient medical data or information available concerning the safety or effectiveness of the Myxo Ring;

n) There were risks associated with the Myxo Ring that had not been fully established;

o) Failed to use a consent form and follow consent protocols in place at Northwestern Memorial Hospital relating to the Myxo Ring for procedures involving clinical studies or research being performed on human subjects;

p) The known risks involving the Myxo Ring such as that a coronary artery might be obstructed and a life threatening heart attack might result;

q) The principles set forth in the *Belmont Report* and the *World Association Declaration of Helsinki* were not being followed or adhered to in Dr. McCarthy's use of the Myxo Ring;

r) Principles set forth in the FDA's *Guidance for Industry - Good Clinical Practices* were not being followed or adhered to in Dr. McCarthy's use of the Myxo Ring;

s) The Myxo Ring was not designed or intended for use on patients with rheumatic valve disease and the ring was contraindicated for use on such patients, but that Dr. McCarthy might nonetheless unilaterally opt to implant the Myxo Ring into such patients, including Plaintiff;

t) Dr. McCarthy retained the sole discretion to either include patients in his study, or to exclude patients from his study, such as if an adverse event occurred, such as if a patient suffered a heart attack during a Myxo Ring implant procedure;

u) Dr. McCarthy retained the sole discretion to refuse to inform the patient of an adverse event that occurred while using the Myxo Ring, such as the patient suffering a heart attack;

v) The Myxo Rings in stock were limited in size and only larger sized rings were available, and thus a less than optimal sized ring might be used with additional risks to the patient;

w) Otherwise failed to follow informed consent policies and procedures described above.

ANSWER: **This Defendant denies each and every allegation in Paragraph 13, including, but not limited to, subparagraphs "a" through "w".**

14) As a direct and proximate result of the above failed disclosures, Plaintiff consented to undergoing a mitral valve repair by Dr. McCarthy, whereas Plaintiff otherwise would not have given her consent to the surgery. Likewise, no other reasonable person would have consented to the surgery had they been provided some or all of the above disclosures.

ANSWER: **This Defendant denies each and every allegation in Paragraph 14.**

15) As a direct and proximate result of the foregoing violations, Dr. McCarthy implanted a Myxo Ring into Plaintiff's mitral valve during the November 6, 2006 surgery, whereupon Plaintiff suffered trauma to one of her coronary arteries and a resulting myocardial infarction, thereby causing severe and permanent damage to her heart and other cardiac related injuries.

ANSWER: This Defendant denies each and every allegation in Paragraph 15.

16) Plaintiff thus sustained the following damages:

a) Medical expenses, past and future;

b) Lost employment opportunities, past and future;

c) Loss of a normal life or disability;

d) Pain and suffering, past and future;

e) Loss of life expectancy.

ANSWER: This Defendant denies each and every allegation in Paragraph 16.

WHEREFORE, Defendant, **PATRICK MCCARTHY, M.D.** denies that Plaintiff is entitled to judgment in any amount whatsoever and requests judgment in its favor and against the Plaintiff, including all costs of this action and for such other relief as this Court deems just.

COUNT VIII – MEDICAL BATTERY
Northwestern Memorial Hospital Only – Direct Action

This Defendant makes no answer to Count VIII, and he denies that he is obligated to do, as it is not directed at this Defendant, and it has previously been dismissed by this Court on August 16, 2010.

COUNT IX – MEDICAL BATTERY
Dr. McCarthy/NWMFF and Northwestern Memorial Hospital via Agency

1) Plaintiff realleges and reaffirms Paragraphs 1 through 28 of the General Allegations as and for this paragraph.

ANSWER: This Defendant repeats and hereby incorporates by reference his answers to Paragraphs 1 through 28 of Plaintiff's Third Amended Complaint as his answers to Paragraph 1 of Count IX of Plaintiff's Third Amended Complaint as if fully set forth herein.

2) In regard to the consent obtained from Plaintiff, or lack thereof, and at all relevant times relating thereto, Dr. McCarthy was employed by NWMFF and all acts and omissions on his part were in the course and scope of his employment thereby.

ANSWER: **This Defendant admits only that he was employed by Northwestern Medical Faculty Foundation. This Defendant denies the remaining allegations of Paragraph 2 of Count IX to the extent that they exceed or are inconsistent with the foregoing.**

3) In regard to the consent obtained from Plaintiff, or lack thereof, and at all relevant times relating thereto, Dr. McCarthy was the apparent agent of Northwestern Memorial Hospital and all acts and omissions on his part were in the course and scope of his agency.

ANSWER: **This Defendant denies each and every allegation in Paragraph 3.**

4) In and prior to November of 2006, Northwestern University established and adopted policies and procedures involving medical research performed on human subjects, and involving the use of medical devices on human subjects. These policies and procedures applied to and were binding upon Dr. McCarthy, as a Professor of Medicine at Northwestern University.

ANSWER: **This Defendant admits only that in and prior to November of 2006, Northwestern University established and adopted policies and procedures involving medical research performed on human subjects, and involving the use of medical devices on human subjects. This Defendant denies the remaining allegations in Paragraph 4.**

5) In and prior to November of 2006, the above referenced Northwestern University policies and procedures also applied to and were binding upon Northwestern Memorial Hospital and its staff physicians, including Dr. McCarthy, in that the research and studies on human studies were performed at the hospital and the hospital provided the patients on whom the research was conducted.

ANSWER: **This Defendant denies each and every allegation in paragraph 5.**

6) From March 15, 2006 through November 19, 2007, Dr. McCarthy performed a clinical study involving the Myxo Ring. Dr. McCarthy published the results of his study in the *Journal of Thoracic and Cardiovascular Surgery* on February 12, 2008. In it, Dr. McCarthy claimed that 124 patients were involved in the study, all of whom suffered myxomatous disease. He claimed to have implanted the Myxo Ring into 100 human subjects.

ANSWER: This Defendant denies each and every allegation in paragraph 6.

7) During and prior to November of 2006, Dr. McCarthy and one other hospital colleague were the only surgeons in the world using the Myxo Ring. The device was not at the time commercially available.

ANSWER: This Defendant denies the allegations in Paragraph 7.

8) The policies and procedures referenced above include the following:

a) Establishes an Institutional Review Board (IRB) for the purpose of reviewing and approving clinical studies and research on human subjects.

b) Requires IRB review and approval of clinical studies performed on human subjects.

c) Requires IRB review and approval of studies involving the use of investigational medical devices on human subjects.

d) Requires that clinical studies are conducted in compliance with applicable governmental regulations, including those set forth in The Department of Health and Human Services (HHS) regulations 45 CFR Part 46 involving the Protection of Human Subjects, 45 CFR 46.101 through 46.124. For example:

(1) 45 CFR 46.108(b) and 46 CFR 109 require IRB review and either approval or disapproval of research activities involving human subjects;

(2) 45 CFR 46.111sets criteria for IRB approval of research and clinical studies involving human subjects;

(3) 45 CFR 46.111(a)(4) requires advanced IRB approval of the informed consent to be provided to the patients involved in a study;

(4) 45 CFR 46.116 sets criteria for an effective informed consent and requires disclosure of the study, a description of the study, an explanation of its purpose and the procedures, identification of procedures that are experimental, disclosure of risks, disclosure of alternative procedures or courses of treatment, whether compensation is available for injuries, whether treatments are available if injuries occur, notice that participation is voluntary, and circumstances under which the participant's participation in the study may be terminated without the patient's consent;

(5) 21 CFR 46.116 prohibits research on human subjects unless an effective informed consent is obtained that includes disclosure of the study, its

purpose, the procedures, disclosure of experimental aspects of the procedure, risks, treatment alternatives, whether compensation is available for injuries, whether treatments are available if injuries occur, and circumstances under which the participant's participation in the study may be terminated without the patient's consent; and

(6) 45 CFR 46.117 requires written documentation of the informed consent with a consent form approved by an IRB.

e) Requires that clinical studies are conducted in compliance with applicable governmental regulations, including those set forth in The Food and Drug Administration (FDA) regulations 21 CFR Parts 50 and 56 involving medical devices regulated by the FDA. These regulations include 21 CFR 50.25 concerning the elements of informed consent; and 21 CFR 50.27 that requires a written consent form approved by the IRB and signed and dated by the patient. Part 56 comprises a body of regulations that establish the duties and responsibilities of IRBs relating to medical device studies.

f) Requires that all investigators and research staff comply with its policies including the federal regulations at 45 CFR 46, 21 CFR 50 and 21 CFR 56.

g) Independently requires informed consent procedures consistent with those embodied in the foregoing federal regulations. In informing patients of the reason for the study, the policies require that the patient be told whether the device has been approved or cleared by the FDA, whether it is experimental, and whether the device is being used for a purpose not approved by the FDA.

h) As part of the informed consent, requires that the patient be informed of risks that cannot be predicted where risks are not fully established, and be told that risks have not been fully established.

i) Identifies an "Investigational Medical Device" as one that is subject to an investigation to evaluate the safety and/or effectiveness of the device.

j) Defines "Significant Risk Devices" as those that are (1) intended as an implant; or (2) used in supporting or sustaining life; or (3) of substantial importance in diagnosing, curing, mitigating or treating disease or otherwise prevents the impairment of human health; or (4) otherwise presents a potential for serious risk to the health, safety, or welfare of the patient, and is consistent with 21 CFR 812.3(m).

k) Identifies annuloplasty rings, such as the Myxo Ring, as a "Significant Risk Device."

l) Recognizes that the FDA may grant an "Investigational Device Exemption" (IDE)

and thereby allow an Investigational Medical Device to be used in a clinical study prior to obtaining the FDA's Premarket Approval (PMA), but clinical evaluation of devices that have not been cleared for marketing by the FDA require IDE approval by the Northwestern IRB, and also require approval of the study by the FDA where the study involves a 'Significant Risk Device."

m) Requires labeling of an Investigational Device as one for investigational use only.

n) Adopts the *Belmont Report* of the Ethical Principles and Guidelines for the Protection of Human Subjects of Research. This requires that all human subject research investigators treat patients as autonomous agents having the right to make their own informed decisions.

o) Agreed to adhere to *The World Association Declaration of Helsinki* in conducting research on human subjects.

p) Agreed to adhere to the FDA's *Guidance for Industry - Good Clinical Practice (E6)* dated April 1996.

ANSWER: **This Defendant lacks sufficient knowledge to either admit or deny the same but demands strict proof thereof.**

9) The foregoing policies and procedures establish that:

a) The Myxo Ring clinical study that Dr. McCarthy conducted from March 15, 2006 through November 19, 2007 and was the subject of his published clinical study in February of 2008, was a clinical study involving human subjects that was subject to the above described policies, procedures and regulations.

b) The Myxo Ring used by Dr. McCarthy and which was the subject of his clinical investigation and study was, as of November 2006, an "Investigational Medical Device."

c) The Myxo Ring was, as of November 2006, a "Significant Risk Device" requiring approval by the Northwestern IRB, and FDA approval of an IDE, prior to conducting a the clinical study involving human subjects and prior to implanting the Myxo Ring into human subjects.

d) The Myxo Ring had not been cleared or approved by the FDA as of November 2006 and approval of an IDE by the FDA was required in November of 2006 prior to conducting a clinical study involving human subjects and prior to implanting the Myxo Ring into human subjects.

e) Specific consent procedures and consent forms following the policies and regulations and approved by the IRB were required for Dr. McCarthy to use and implant the Myxo Ring into human subjects.

f) The Myxo Ring was not intended for use in humans whose mitral valves had rheumatic disease. Any use of the Myxo Ring in a patient with rheumatic disease required specific consent to use the device for this unapproved purpose.

ANSWER: This Defendant denies each and every allegation in Paragraph 9.

10) During and prior to November 2006, the FDA had not cleared or approved the Myxo Ring. The FDA had not approved an IDE for use of the Myxo Ring. The Northwestern IRB had not approved Dr. McCarthy's study, nor his use of the Myxo Ring on human subjects. No consent procedure, protocols or consent forms had been created or approved for use of the Myxo Ring on human subjects. No consent procedure, protocols or forms had been created or approved for use of the Myxo Ring on patients with rheumatic disease.

ANSWER: This Defendant denies each and every allegation in Count 10.

11) On September 21, 2006, Dr. McCarthy met with Plaintiff. Dr. McCarthy informed Plaintiff that she required surgery on her mitral valve. He informed Plaintiff that pre-operative studies showed that she suffered from myxomatous disease, but did not show the presence of rheumatic disease. Dr. McCarthy informed Plaintiff, among other things, that he would perform a repair of the valve using an annuloplasty ring unless, during the surgery, he found rheumatic disease. If rheumatic disease was present, Dr. McCarthy informed Plaintiff that she would require a mitral valve replacement rather than a repair.

ANSWER: This Defendant admits only that certain medical records reveal that this Defendant met with Plaintiff on September 21, 2006, and that he informed Plaintiff that she required surgery on her mitral valve. Further answering, this Defendant admits only that pre-operative studies showed that Plaintiff had myxomatous disease, but did not show the presence of rheumatic disease. This Defendant denies the remaining allegations of Paragraph 11 of Count VII to the extent that they exceed or are inconsistent with the foregoing.

12) On October 10, 2006, Plaintiff met with other members of Dr. McCarthy's team. Consent forms relating to her surgery were presented and signed. Neither Dr. McCarthy nor the other members of his team informed Plaintiff that Dr. McCarthy intended to implant a Myxo Ring

into Plaintiff's mitral valve; the Myxo Ring was not cleared or approved by the FDA; the Myxo Ring was an investigational or experimental medical device; Dr. McCarthy was using and implanting the Myxo Ring into patients as part of a clinical study he was conducting on human patients; neither Northwestern University, its IRB, nor the hospital had approved or authorized Dr. McCarthy's study; Dr. McCarthy invented, owned patent rights in, and received royalties on the Myxo Ring; or that Dr. McCarthy was using and implanting the Myxo Ring into patients in violation of numerous University policies and procedures, and in violation of federal regulations that governed the use of medical devices and the performance of clinical research on human subjects. Neither Dr. McCarthy nor the members of his team informed the Plaintiff that the Myxo Ring carried a risk of an obstruction to the coronary artery. Nor did Dr. McCarthy or any other member of his medical team inform Plaintiff that even though the Myxo Ring was contraindicated where rheumatic disease was present, Dr. McCarthy might nevertheless unilaterally opt to implant the device into a patient.

ANSWER: This Defendant denies each and every allegation in Paragraph 12.

13) On November 6, 2006, Dr. McCarthy performed open heart surgery upon Plaintiff. During the surgery he implanted a Myxo Ring into the Plaintiff's mitral valve. His operative report and other writings state that during the surgery, he found the presence of rheumatic disease. Dr. McCarthy nonetheless selected and implanted a Myxo Ring into Plaintiff's mitral valve.

ANSWER: This Defendant admits On November 6, 2006, Dr. McCarthy performed open heart surgery upon Plaintiff. During the surgery he implanted a Myxo Ring into the Plaintiff's mitral valve. His operative report and other portions of the medical records state that during the surgery, he found the presence of rheumatic disease. Dr. McCarthy selected and implanted a Myxo Ring into Plaintiff's mitral valve. This Defendant denies the remaining allegations of Paragraph 13 of Count VII to the extent that they exceed or are inconsistent with the foregoing.

14) Dr. McCarthy selected the Myxo Ring, and surgically attached it to Plaintiff's mitral valve during the November 6 2006 surgery. Dr. McCarthy's decision to and act of implanting a Myxo Ring into Plaintiff was thus knowing, purposeful and intentional.

ANSWER: This Defendant admits only that Dr. McCarthy selected the Myxo Ring, and surgically attached it to Plaintiff's mitral valve during the November 6 2006 surgery. This Defendant denies the remaining allegations of Paragraph 14 of Count VII to the extent that

they exceed or are inconsistent with the foregoing.

15) The selection and implantation of a Myxo Ring into Plaintiff's mitral valve was offensive in numerous respects. The Myxo Ring was implanted into Plaintiff's mitral valve without her knowledge that (a) the Myxo Ring was not cleared or approved by the FDA; (b) the Myxo Ring was investigational or experimental; (c) the Myxo Ring required but had not received FDA approval of an IDE; (d) the Myxo Ring required but had not received IRB approval for use of an IDE; (e) Dr. McCarthy might implant the Myxo Ring into her mitral valve as part of a clinical study that required FDA and Northwestern IRB approval and that neither approval had been obtained; (f) Dr. McCarthy might or might not include her in the study and reserved the discretion to remove her from the study without her knowledge or consent in the event she suffered an adverse event, such as a heart attack, while his device was being implanted; (g) Dr. McCarthy might use and implant the Myxo Ring into her heart valve without following and contrary to policies governing clinical studies and research on human subjects; (h) Dr. McCarthy invented, owned patent rights in, and earned royalties on the Myxo Ring that he was implanting into human subjects and had a vested interest in the outcome of his study; (i) the Myxo Ring carried a risk of trauma to her coronary arteries and a resulting heart attack; (j) the Myxo Ring was new and under investigation and it carried potential risks which were then unknown; (k) Dr. McCarthy also reserved the right to not disclose to Plaintiff whether she even suffered an adverse event, such as a heart attack, during the surgery; and (l) the Myxo Ring was contraindicated for patients with rheumatic disease and that Dr. McCarthy retained the exclusive discretion to implant the Myxo Ring into her heart valve even if he found rheumatic disease during surgery even if it subjected Plaintiff to additional risks of harm.

ANSWER: This Defendant denies each and every allegation in Paragraph 15.

16) The surgery performed by Dr. McCarthy upon the Plaintiff on November 6, 2006 was substantially at variance with the information provided to Plaintiff and at variance with the consent Plaintiff provided. The Plaintiff never consented to having Dr. McCarthy use a Myxo Ring that was investigational or experimental; was not FDA approved or cleared; was not IRB approved; lacked FDA approval of an IDE; carried risks that were not known at the time; was or could be part of a clinical study of which she did not know of; might be used by Dr. McCarthy for a contraindicated purpose, such as where rheumatic disease was present; that Dr. McCarthy had conflicting financial interests in the device and in the results of his clinical study; or if she suffered an adverse event during the surgery, such as a heart attack, Dr. McCarthy and hospital personnel might not disclose the event to her.

ANSWER: This Defendant denies each and every allegation in Paragraph 16.

17) As a direct and proximate result thereof, while Dr. McCarthy was implanting a Myxo Ring into Plaintiff's mitral valve on November 6, 2006, Plaintiff's coronary artery was subjected to trauma and Plaintiff thereby suffered a heart attack and other cardiac related injuries.

ANSWER: This Defendant denies each and every allegation in Paragraph 17.

18) Plaintiff thus sustained the following damages:

a) Medical expenses, past and future;

b) Lost employment opportunities, past and future;

c) Loss of a normal life or disability;

d) Pain and suffering, past and future;

e) Loss of life expectancy.

ANSWER: This Defendant denies each and every allegation in Paragraph 18.

WHEREFORE, Defendant, **PATRICK MCCARTHY, M.D.** denies that Plaintiff is entitled to judgment in any amount whatsoever and requests judgment in its favor and against the Plaintiff, including all costs of this action and for such other relief as this Court deems just.

COUNT X – BATTERY
Edwards Lifesciences, LLC Only

This Defendant makes no answer to allegations in Count X and denies that it is obligated to do so, as it is not directed at this Defendant.

COUNT XI – RES IPSA LOQUITUR – MEDICAL DEFENDANTS

1) Plaintiff realleges and reaffirms Paragraphs 1 through 28 of the General Allegations as and for this paragraph.

ANSWER: This Defendant repeats and hereby incorporates by reference his answers to Paragraphs 1-28 of Plaintiff's Third Amended Complaint as his answers to Paragraph 1 of Count XI of Plaintiff's Third Amended Complaint as if fully set forth herein.

2) At all relevant times, Northwestern Memorial Hospital and the NMFF, individually and through its agent, Dr. McCarthy, and Dr. McCarthy, individually, were under a duty to possess and apply the knowledge and use the skill and care required of reasonably well-qualified cardiac surgeons.

ANSWER: This Defendant admits that he was employed by Northwestern Medical

Faculty Foundation, but denies all the remaining allegations in Paragraph 2.

3) At all relevant times up to and including the time the Myxo Ring was implanted into Plaintiff's mitral valve, the valve was under the exclusive and consecutive management and control of Northwestern Memorial Hospital, MWMFF, and Dr. McCarthy.

ANSWER: This Defendant denies each and every allegation in Paragraph 3.

4) In the ordinary course of events, the injury to the Plaintiff's heart injury would not have occurred if Dr. McCarthy had used a reasonable standard of care while the surgery was under his management.

ANSWER: This Defendant denies each and every allegation in Paragraph 4.

5) Plaintiff thus sustained the following damages:

a) Medical expenses, past and future;

b) Lost employment opportunities, past and future;

c) Loss of a normal life or disability;

d) Pain and suffering, past and future;

e) Loss of life expectancy.

ANSWER: This Defendant denies each and every allegation in Paragraph 5.

WHEREFORE, plaintiff, MAUREEN OBERMEIER, prays for judgment against the Defendants, NORTHWESTERN MEMORIAL HOSPITAL, THE NORTHWESTERN MEDICAL FACULTY FOUNDATION, and PATRICK MCCARTHY, M.D., jointly and severally, in a sum sufficient to appropriately compensate her for her aforesaid damages, which are well in excess of the jurisdictional minimum of this court, plus costs.

COUNT XII – MEDICAL NEGLIGENCE
Patrick McCarthy, MD/NWMFF and Northwestern Memorial Hospital – via agency

1) Plaintiff realleges and reaffirms Paragraphs 1 through 28 of the General Allegations as and for this paragraph.

ANSWER: This Defendant repeats and hereby incorporates by reference his answers to Paragraphs 1-28 of Plaintiff's Third Amended Complaint as his answers to Paragraph 1 of

Count XII of Plaintiff's Third Amended Complaint as if fully set forth herein.

2) In and prior to November 2006 and at all times relevant herein, Dr. McCarthy was employed by NWMFF and all acts and omissions on his part were in the course and scope of his employment thereby.

ANSWER: This Defendant admits only that he was an employee of Northwestern Medical Faculty Foundation. This Defendant denies the remaining allegations of Paragraph 2 of Count XII to the extent that they exceed or are inconsistent with the foregoing.

3) In and prior to November 2006 and at all times relevant herein, Dr. McCarthy was the apparent agent of Northwestern Memorial Hospital and all acts and omissions on his part were in the course and scope of his agency.

ANSWER: This Defendant denies each and every allegation in Paragraph 3.

4) In November of 2006, Northwestern Memorial Hospital was the sole hospital at which the Myxo Ring was being used. Dr. McCarthy and one other hospital colleague were the sole physicians in the world using the Myxo Ring. Myxo Rings were not commercially available in November 2006.

ANSWER: This Defendant denies each and every allegation in Paragraph 4.

5) The Myxo Ring is an annuloplasty ring which, in November 2006, was intended to for use solely on patients with myxomatous disease. The Myxo Ring was contraindicated for patients having rheumatic changes in their mitral valve. Where rheumatic changes are present, the proper procedure and standard of care was to replace, rather than repair, the mitral valve. The Myxo Ring is not intended for use in valve replacement procedures.

ANSWER: This Defendant denies each and every allegation in Paragraph 5.

6) The Myxo Ring is larger in size than other comparable rings that were available in November of 2006. At the time of Plaintiff's November 6, 2006 surgery, Dr. McCarthy did not have available to him smaller sized Myxo Rings. The larger Myxo Rings are more likely to come into closer proximity and subject trauma to a patient's coronary arteries than the other smaller comparable rings, by virtue of Myxo Ring's larger size.

ANSWER: This Defendant denies each and every allegation in Paragraph 6.

7) From March 15, 2006 through November 19, 2007, Dr. McCarthy performed a clinical study involving the Myxo Ring. Dr. McCarthy published the results of his study in the

Journal of Thoracic and Cardiovascular Surgery on February 12, 2008. In it, Dr. McCarthy claimed that 124 patients were involved in the study, all of whom suffered myxomatous disease. He claimed to have implanted the Myxo Ring into 100 human subjects. This study discusses the intended use of the Myxo Ring, sizing issues, and his standard methods and practices.

ANSWER: This defendant denies each and every allegation in paragraph 7.

10 (sic)) Dr. McCarthy performed a mitral valve repair on Plaintiff on November 6, 2006. During the surgery, Dr. McCarthy observed and noted the presence of rheumatic disease in the mitral valve. He nonetheless performed a valve repair rather than a valve replacement, and he nonetheless used a large 36 mm Myxo Ring during the repair.

ANSWER: This Defendant admits only that certain medical records reveal that this Defendant performed a mitral valve repair on Plaintiff on November 6, 2006. Further answering, certain medical records reveal that there was minimal rheumatic disease in the mitral valve and that this Defendant used a 36 mm Myxo Ring to perform the repair. This Defendant denies the remaining allegations of Paragraph 10 of Count XII to the extent that they exceed or are inconsistent with the foregoing.

11 (sic)Dr. McCarthy, individually and as the agent and employee of NWMFF and Northwestern Memorial Hospital, was under a duty to apply the skill and care of a reasonably well qualified cardiac surgeon under like or similar circumstances.

ANSWER: This Defendant admits only that he owed that duty imposed on him by law, if any, and denies any further allegations in Paragraph 11 of Count XII of Plaintiff's third Amended Complaint to the extent that they exceed or are inconsistent herewith. This Defendant specifically denies that he was an agent or employee of Northwestern Memorial Hospital.

12 (sic) In violation of the aforesaid duty, Dr. McCarthy committed one or more of the following negligent acts or omissions:

a) Despite the presence of rheumatic changes, performed a valve repair rather than a valve replacement;

b) Selected and implanted a Myxo Ring into Plaintiff's mitral valve despite the presence of rheumatic changes;

c) Used a large 36 mm Myxo Ring rather than a more optimal ring;

d) Failed to adequately assess the Plaintiff's cardiac status during the surgery;

e) Failed to adequately investigate the Plaintiff's cardiac anatomy and determine the location of her circumflex artery;

f) Failed to properly identify the coronary arteries;

g) Harmed, damaged or traumatized one or more of the coronary arteries;

h) Failed to investigate or assess the cause of the harm to one or more of the coronary arteries;

i) Failed to adequately monitor the Plaintiff; and

j) Otherwise treated Plaintiff in a negligent manner.

ANSWER: This Defendant denies each and every allegation in Paragraph 12, including but not limited to, subparagraphs "a"-"j".

13 (sic) As a direct and proximate result thereof, one or more of plaintiff's coronary arteries were damaged, causing her to suffer a severe cardiac episode which, in turn, severely damaged her heart muscles and otherwise harmed her cardiac status.

ANSWER: This Defendant denies each and every allegation in Paragraph 13.

14 (sic)) Plaintiff thus sustained the following damages

a) Medical expenses, past and future;

b) Lost employment opportunities, past and future;

c) Loss of a normal life or disability;

d) Pain and suffering, past and future;

e) Loss of life expectancy.

ANSWER: This Defendant denies each and every allegation in Paragraph 14.

WHEREFORE, Defendant, **PATRICK MCCARTHY, M.D.** denies that Plaintiff is entitled to judgment in any amount whatsoever and requests judgment in its favor and against the Plaintiff, including all costs of this action and for such other relief as this Court deems just.

Respectfully yours,

ANDERSON, RASOR & PARTNERS, LLP

One of the Attorneys for Defendant,
Patrick McCarthy, M.D.

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AFFIDAVIT OF SERVICE

The undersigned on oath deposes and says that she served a true and correct copy of the foregoing **PATRICK MCCARTHY, M.D.'S ANSWER TO PLAINTIFF'S THIRD AMENDED COMPLAINT AT LAW** to:

Ardwin E. Boyer
Newman, Boyer & Statham, Ltd.
20 N. Clark Street, Suite 800
Chicago, IL 60602

David C. Jensen
Robert J. Feldt
Kirk D. Bagrowski
Eichhorn & Eichhorn, LLP
200 Russell Street
P.O. Box 6328
Hammond, IN 46325

by placing said copy in a postage prepaid, correctly addressed envelope and depositing in the mail facility at 100 S. Wacker Drive, Chicago, Illinois, on August 19, 2011, before 5:00 P.M.

Patricia J. McClintock

SUBSCRIBED and SWORN to before
me this 19th day of August, 2011.

Sharon F. Dinovo
Notary Public

"OFFICIAL SEAL"
SHARON F. DINOVO
Notary Public, State of Illinois
My Commission Expires 09/27/14