AFFIDAVIT

SAMPLE NO.

STATE OF: Minnesota

COUNTY OF: Hennepin

Before me, Sharon L. Matson, CSO, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508) effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Nalini M. Rajamannan, MD in the county and state aforesaid, who, being duly sworn, deposes and says:

I am the Medical Director at Most Sacred Heart of Jesus Cardiology and Valvular Institute, 703 North 8th Street, Sheboygan, WI 53081, 920-451-4611; and, was an Associate Professor at Northwestern University, Chicago, IL from 2000 to 2011. I can be reached at 312-498-9496 (cell).

On 12/10/2018 I came to the U.S. FDA Minneapolis District Office (MIN-DO), 250 Marquette Ave., #600, Minneapolis, MN 55401 to report a patient death related to a heart valve implanted under research conditions. I was accompanied by the son of the patient and local news representatives, and we were stopped. I subsequently sent an email to Michael Dutcher, DVM and District Director of MIN-DO regarding "Reporting an Adverse event today". I was contacted by Sheila vanTwuyver, Consumer Complaint Coordinator for MIN-DO on 12/11/2018, and I subsequently provided the following written statements to her.

On 12/11/2018 I provided the following information in an email to Ms. vanTwuyver:

"URGENT: IMMEDIATE ATTENTION FOR FDA INSPECTORS!

December 11, 2018

Dear Sheila
Thank you for your prompt response.

The Knotts family suffered the worst loss on Thanksgiving Day, the death of their beloved husband, father and grandfather secondary to the failed heart surgery of a mitral valve repair on September 25, 2014.

William Knotts received a 34 mm physio ring during surgery at Northwestern Memorial Hospital by Dr. Patrick McCarthy. After surgery, the Mr. Knotts never felt well. He was short of breath with exertion and at rest for the next three and a half years, and never received answers to why he had continued symptoms.

Nalini M. Rajamannan, MD
AFFIANT'S SIGNATURE AND TITLE

Most Sacred Heart of Jesus Cardiology and Valvular Institute
FIRM'S NAME AND ADDRESS (Include ZIP Code)
703 N 8th St, Sheboygan, WI 53081

Subscribed and sworn to before me at Minneapolis, MN (City and State),

this 19th **day of** December, **20** 18.

Sharon L Matson
(Employee's Signature)

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.

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When Mr. Knotts left the operating room on September 25, 2014, the surgery performed by Dr. Patrick McCarthy. See Attached operative note. When he left the operating room, Mr. Knotts had a gradient across the mitral valve of 12 mm Hg. Normal should be less than 2 mm Hg.

This gradient was measured and confirmed at various institutions including University of Chicago, the Mayo Clinic and also during the heart surgery at Northwestern Memorial Hospital.

After years of shortness of breath, Mr. Knotts consulted with myself on April 25, 2018, and I recommended that he get several opinions regarding the severe mitral stenosis resulting from the first surgery. After consultations with several surgeons, Mr. Knotts chose to go to Christ Hospital in Oaklawn, IL to have a second surgery to remove the diseased valve.

The second surgery occurred on June 1, 2018 and he was in the operating room for 12 hours with episodes of cardiac arrest. He then was in the hospital for 174 days and transferred to Shirley Ryan rehab in November 2018, and then died in the intensive care unit at Northwestern Memorial Hospital secondary to a bleed into his brain on November 22, 2018.

On November 24, 2018, I informed Northwestern University IRB, President of Northwestern U, the general counsel, the board of trustees etc. of the death of the patient as Mr. Knotts had an experimental protocol performed during the September 25, 2014 surgery. A protocol which was recently discovered to be a terminated Northwestern FDA IRB protocol from 2007, as discovered by FDA Inspectors on August 8, 2008.

Upon review of Mr. Knotts operative record on September 25, 2014, he had undergone a technique to measure the patient's mitral valve leaflet using a caliper 1155 as outlined in the attached memo submitted to the United States Senate Committee.

The company Edwards Lifesciences had developed the caliper for measurements of the three scallops of the anterior(front) and posterior(back) leaflets of the mitral valve. The specific measurements are A1, A2,A3 and P1,P2,P3.

AFFIANT'S SIGNATURE AND TITLE Nalini M Rajamannan MD

FIRM'S NAME AND ADDRESS *(Include ZIP Code)* Most Sacred Heart of Jesus Cardiology and Valvular Inst 703 N 8th St Sheboygan WI 53081

Subscribed and sworn to before me at Minneapolis, MN,
(City and State)

this 19th day of December, 20 18.

[signature]
(Employee's Signature)

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These measurements were specific to a protocol 1532-004, attached to the Senate Judiciary Committee letter, March 2014, which Dr. McCarthy had developed to measure the valve during a prospective clinical trial to repair myxomatous mitral valve disease, or mitral valve prolapse, see attached publication of July 2008.

I was a member of the study team and helped to write the first report, see attached, but removed my participation in May 2007. At this time, I learned of the first victim, Ms. Vlahoulis, who needed a second heart surgery and that she had never signed a form for consent to be in the prospective trial.

In May 2007, I reported the event to Northwestern University IRB, Northwestern Memorial Hospital, and the Dean's office. The University's IRB coordinator Ms. Osafo, reviewed the protocol in May 2007, and asked the surgeon Dr. McCarthy to cease and desist the protocol 1532-004. The protocol included prospective study on the patients testing of the model 5100 ring and the use of the 1155 caliper measurements. Since Dr. McCarthy chose to terminate the study, see attached record, and not submit the proper paperwork to follow the FDA IRB regulatory pathway for reporting prospective testing of a heart devices and the measurement technique cited under the IRB protocol 1532- 004.

Dr. McCarthy instead of complying with his own termination order, he continued to perform the caliper measurements on several patients at least until year 2014 as recorded in Mr. Knotts operative report, if not year 2018, which included hundreds if not thousands of patients.

I know of four other patients who have suffered severe side effects from the failed mitral valve repair surgery, who have consulted in my practice in Chicago and in Wisconsin. These patients have had heart attacks and reoperations, and all of them have also needed pacemakers and defibrillators etc from the damage sustained during the surgery.

Now that the Knotts' 2014, operative record proves that Dr. McCarthy continued to perform the caliper measurements after the University IRB coordinator issued the cease and desist on June 28, 2007, and

AFFIANT'S SIGNATURE AND TITLE

Nalini Rajamannan MD

FIRM'S NAME AND ADDRESS *(Include ZIP Code)*

[illegible] 703 N 5th St [illegible] WI 53081

Subscribed and sworn to before me at Minneapolis, MN *(City and State)*,

this 19th **day of** December, 20 18.

Sharon L Matson

(Employee's Signature)

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Mr. Knotts who has now died. The FDA must take immediate action to investigate the other victims, Vlahoulis, Edwards, Warshawsky, Obermeier, who have suffered from reoperations, deaths, and heart attacks, since the initial study of March 2006. All of whom also received the experimental caliper mis sizing technique, closed by Osafo on June 28, 2007 for not reporting the prospective nature of the clinical study which began in March 2006.

In 2018, there could be close to 2000 patients who may have got the terminated experimental caliper protocol 1532-004, which could have sized the ring incorrectly as Dr. McCarthy failed to follow Edwards Lifesciences published Directions for Use for annuloplasty rings, which are attached in this email, and failing to follow Northwestern University FDA IRB cease and desist order.

The immediate action by the FDA should be to 1) place a hold on the terminated protocol 1532-004 and 2) place a hold on all of Dr. McCarthy's past, current and future surgeries, 3) review all mitral valve repair records which placed patients at risk for stenosis, heart attacks, reoperations and deaths and 4) to place cease and desist order on all IRB research protocols for Dr. McCarthy, who has failed to follow the regulatory pathway as outlined by Northwestern University, the FDA and also Edwards Lifesciences and has caused deaths as recent as November 22,
2018.

https://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ComplianceEnforcement/ucm369514.htm

Steven Knotts a resident of MN whose father died on Thanksgiving from the terminated experimental protocol which Edwards Lifesciences never adopted in the directions for use for their FDA cleared annuloplasty rings, and myself a native Minnesotan and Adjunct physician scientist at the Mayo Clinic, with an affiliation of all of my graduate school training at the Mayo Clinic since 1985, and IRB experience at the Mayo Clinic and Northwestern University, can
meet with you this week at the FDA in your Minneapolis to review the evidence.

The evidence is clear, the protocol was terminated by IRB coordinator Osafo in May 2007, because Dr.

AFFIANT'S SIGNATURE AND TITLE
[illegible] MD

FIRM'S NAME AND ADDRESS (Include ZIP Code)
[illegible]

Subscribed and sworn to before me at Minneapolis, MN (City and State),

this 19th day of December, 2018.

[illegible]
(Employee's Signature)

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FORM FDA 463a (5/07)

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McCarthy failed to identify the prospective nature of the clinical research trial, patients have been injured with a recent death as reported to the University on November 24, 2018, and now to the FDA, and there may be thousands of patients who were asleep under anesthesia, since 2006, who never knew they were experimented on with the calipers, and who
should have received the confirmed FDA approved Directions for use which was approved by the FDA for the Edwards Lifesciences Sizing instructions for annuloplasty rings.

Thank you again for your prompt response and I hope the FDA places an immediate hold on the protocol 1532-004 experimental sizing measurements to protect future patients from being injured and or succumbing to death from the failed repair.

Nalini Marie Rajamannan, MD, FACC
Most Sacred Heart of Jesus Cardiology and Valvular Institute
Corvita Science Foundation
Mayo Clinic Department of Biochemistry and Molecular Biology"

On 12/12/2018 at 11:40 AM I provided the following additional information in an email to Ms. vanTwuyver, copied to several individuals including representatives at Kare 11 news, the U.S. Senate, and U.S. House of Representatives:

"Dear Sheila

One quick clarification, all of the victims thought they were receiving the standard of care from Dr McCarthy.

They were told they would get FDA cleared annuloplasty rings with the FDA approved directions for use.

All of the victims listed including Mr Knotts father got the measurements outlined in the 2006 1532-004 protocol, which Northwestern IRB terminated officially on June 28, 2007.

AFFIANT'S SIGNATURE AND TITLE

N L M R MD

FIRM'S NAME AND ADDRESS *(Include ZIP Code)*

Most Sacred Heart of Jesus Cardiology and Valvular Institute
703 N 8th St Sleepy Eye MN 56085

Subscribed and sworn to before me at Minneapolis, MN *(City and State)*,

this 19th **day of** December, **20** 18.

Sharon L Matson

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The failure to follow the Edward's Lifesciences DFU is the cause of Mr Knotts death.

We are available to meet at your office to review the evidence.

Nalini Rajamannan, MD"

Later on 12/12/2018, at 7:17 PM I provided the following additional information in an email to Ms. vanTwuyver:

"Dear Sheila

Please convey to the investigators, that the caliper measurements were never approved by Edwards Lifesciences and the FDA 510k clearance for the annuloplasty rings manufactured by Edwards Lifesciences.

I am attaching the directions for use for the model 5100.

The caliper measurements were part of the experimental protocol Northwestern University had terminated back on June 28, 2007.

Any patient who underwent mitral valve surgery and the surgeon used the Edwards Lifesciences rings, the correct operative technique would be to use the standard sizer which is listed in the DFU on the attached documents.

I have 5 patients who have been injured, and one who died. There is another patient who recently died, and who underwent a mitral valve surgery by the surgeon from Northwestern University.

Nalini"

AFFIANT'S SIGNATURE AND TITLE

MD

FIRM'S NAME AND ADDRESS *(Include ZIP Code)*

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this 19th **day of** December, **20** 18.

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I attached the following documents to that email:
-device model 5100 directions for use, titled "Edwards Myxo ETlogix Annuloplasty Ring Implantation Techniques", dated 2007 (14 pages); and,
-Trademark information for the Myxo Etlogix device, showing Registration Date Jan. 5, 2008 owned by Edwards Lifesciences Corporation, One Edwards Way, Irvine, CA 92614.

On 12/19/2018 I met with the FDA Bioresearch Monitoring (BIMO) West Program District Director Eric Pittman and Consumer Safety Officer Sharon Matson at MIN-DO to provide additional details of my concerns, documents, and to request follow-up by FDA. I was accompanied by Steve Knotts, Minneapolis, MN, son of the deceased patient Bill Knotts; Chess Obermeier, California, husband of a patient Maureen Obermeier; and, Brian Warshawsky, California, patient.

I believe Dr. McCarthy continued his prospective experimental protocol 1532-004 using an unapproved mitral valve caliper measuring tool after he was told to stop by his reviewing IRB on 6/28/2007; that the use of the calipers instead of the standard sizing device led to mis-sizing of mitral rings which has led to serious adverse events for patients including death; and, I am extremely concerned that he continued and is continuing in these procedures with other patients. This is also the 4th clinical trial Dr. McCarthy has conducted without getting patient informed consent, that I'm aware of, with the others being a Batista study, Atricure, Edwards Model 4100 study in addition to the Edwards Model 5100 and calipers Model 1155.

I identified and provided copies of the documents to FDA as described in this statement. I have reviewed this affidavit and affirm it is true and accurate.

SCM/mm

AFFIANT'S SIGNATURE AND TITLE

N L M [illegible] MD

FIRM'S NAME AND ADDRESS *(Include ZIP Code)*

[illegible]

Subscribed and sworn to before me at Minneapolis, MN *(City and State)*,

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SLM [initials] NMR [initials]

AFFIANT'S SIGNATURE AND TITLE

[signature] MD

FIRM'S NAME AND ADDRESS *(Include ZIP Code)*

[illegible] of [illegible]
503 N 5th St [illegible] WI 53081

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