

FDA FOIA Documents: Circuit Court Filings Confirm Termination of Human Heart Study at Northwestern University

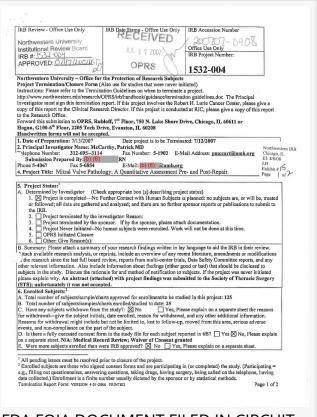
FDA FOIA documents reveal evidence in a ten year old case providing a legal pathway to request for a new trial. Press release provides links for US Citizens.

SHEBOYGAN, WISCONSIN, USA, May 13, 2019 /EINPresswire.com/ -- The final clues are falling into place in a 12-year-old mystery about how patient protections were bypassed during open heart surgery for hundreds of patients and published in the American Association of Thoracic Surgeons Journal.

The Model 5100 heart valve ring was implanted into nearly 700 patients without their consent or approval from the Food and Drug Administration.

Documents recently obtained through a Freedom of Information Act request outline how this practice escaped regulatory notice and notice of the Judge and plaintiff's attorney in the civil case 08-L-012426 Circuit Court of Cook County.

Link to Public Court Documents: https://www.scribd.com/document/401704498/Pla ntiffPetition1401-02222019



FDA FOIA DOCUMENT FILED IN CIRCUIT COURT OF COOK COUNTY

Northwestern's defense attorney from the law firm Anderson Rasor stated in Judge Gomolinski's Chicago courtroom on Dec. 6, 2013 that the federal protocol 1532-004 had nothing to do with a published study on the heart valve.

https://www.scribd.com/document/409805204/120613-motion

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The Truth Shall Set you Free as posted in the Lobby of the Chicago Tribune Building" But the new FOIA documents confirm that after the Federal FDA Inspection, 1532-004 was the study to test the Myxo Ring. The documents also confirm that there was no documentation provided to the University confirming the FDA approval status of the device during the testing.

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https://www.scribd.com/document/407458228/FOIA-FDA-12-18-2018-IHS

"He (the surgeon) was putting it into patients, seeing how it worked, and not telling them," Obermeier's attorney, Adrwin Boyer, said during opening statements of the 2016 court trial in Cook County, according to Fox 32 in Chicago.

Meanwhile, a cardiologist who removed herself from the Model 5100 device study when she realized patients hadn't given their consent, published a report on May 4, 2019, to highlight key facts and documents in the case:

•Batients began receiving the controversial heart valve ring in 2006.

•Ilesting of the device was officially closed by Northwestern University officials as of June 2006, but the final publication of the clinical study published in the American Association of Thoracic Surgery's premier journal in July 2008 reveals that the study continued without patient consent and without the university approval until November 2007 See attached FDA FOIA document. •A press release on Dec. 4, 2008, confirmed the first of many Senate Finance and Senate Judiciary investigations into the Model 5100.

•Dnited States Sen. Charles Grassley (IA) requested evidence as part of the Senate Investigation

Over the six-year investigation, the documents, responses and letters were reviewed by Dr. Nalini Rajamannan, the cardiologist who removed herself from the Model 5100 study.

Rajamannan's report, The Myxo File X and <u>the Myxo Report</u>, offers a comprehensive look at the Senate Finance and Senate Judiciary Investigations from 2008-2014 for the 667 heart valve patients, media, regulators, lawmakers and patients' rights advocates.

The Myxo File X, published on Amazon.com, also provides an in-depth analysis by Dr. Rajamannan, an eye-witness to the human experiments, regarding the release of responses sent to the Senate.

Following is a link to the FDA FOIA documents released on December 18 2019, on the eve of <u>FDA</u> <u>meeting</u> with the heart valve specialist Dr. Rajamannan:

https://www.scribd.com/user/383243128/Nalini-Rajamannan

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

Visit <u>https://www.sacredcardiology.com/</u> for more information about Most Sacred Heart of Jesus Cardiology and Valve Institute

Nalini M. Rajamannan Most Sacred Heart of Jesus Cardiology and Valve Institute +1 312-498-9496 email us here

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