Northwestern University and Edwards Lifesciences Catastrophic Failure to Heed Minneapolis FDA Warnings in 2018

Monday 10 August, 2020

Sheboygan, WI, **In August 2020**, Senior Leadership at one of Chicago's top Universities, Northwestern in Evanston and Chicago, failed to heed Federal Food and Drug Administration warnings to stop experimental heart surgeries over the past decade. Injuries reported to the FDA during a meeting at the Minneapolis District office in December 2018, could have been prevented had the University heeded the FDA warning in 2008.

As of May 2020, there are now over 1000 patients who underwent the experimental research surgery and there is no path to justice to inform patients and doctors of the risk, until the University follows their own Federal Assurance policy to protect patients, policy number 1549, and the FDA follows their own regulations to protect patients in the United States of America.

In 2018, another discovery of the use of an undisclosed device in patients was revealed to the FDA during a meeting held in the Minneapolis District office with victims and their families. During the meeting, the FDA learned of a third device developed by Edwards Lifesciences the Model 1155 caliper measurement tool.

Ten years since the last FDA investigation of Northwestern University, several more victims discovered they were injured by the experimental heart surgery technique to measure their heart valve leaflets. The FDA agreed to a meeting at the Minneapolis District office, after the local press showed up for a press conference in the lobby of the FDA in Minneapolis.

This branch of the FDA is important in the medical device regulation. The patients and their family members, attended a meeting in the Minneapolis FDA for over 3 hours testified to the danger of the experimental surgery, their injuries, and their ongoing complications as related to the devices invented by the heart surgeon and manufactured by Edwards Lifesciences, to develop novel heart valve rings and a novel measurement technique to "size a heart valve."

The patients injuries range from reoperations, severe heart attacks, stroke and death, as published by Northwestern University's own Student Newspaper the Daily Northwestern.

Dr. Rajamannan awaits final decision from the FDA to inform the now 1000 patients affected.

https://www.youtube.com/watch?v=SPfj1SzCw58

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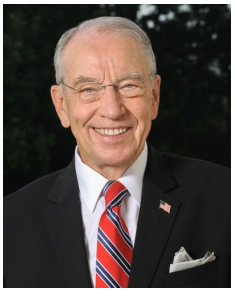

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