Northwestern University and major Heart Valve manufacturer are the Center of the Myxo Cover-Up

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/FROM PR NEWSWIRE DALLAS 888-776-3971/ [STK] [IN] [SU] TO NEWS EDITORS: Northwestern University and major Heart Valve manufacturer are the Center of the Myxo Cover-Up CHICAGO, IL, Sept. 25, 2012 /PRNewswire/ - The Myxo Etiologix model 5100, also known as the Myxo 5100 is a heart valve device manufactured and introduced to the market by Edwards LifeSciences (Irvine CA) in 2007. This device was specifically designed to treat the Myxo disease, an illness that causes a leaky heart valve. Despite being sold and surgically implanted into patients in the US market since 2007, it appears as if the Food and Drug Administration who approves the marketing of all medical devices, was unaware that the Myxo 5100 was on the shelves. In fact, Edwards failed to apply for an investigational device exemption for the Myxo 5100 which is required under FDA law 21 CFR 812.2 in 2006 when the first prototype models were made for human experiments. Northwestern also failed to obtain informed consent from patients which violate the Common Rule 45 CFR 46 which is a requirement in this country.

According to the Public Pair Patent website, Edwards LifeSciences applied for a patent on the device from 2004-2007, which included several claims modifying the shape in order to demonstrate a unique invention. Subsequently these changes resulted in new patent awarded by the United States patent office in 2007. Simultaneously, Edwards claimed in their own internal documents which are termed a justification to file, in 2006, documenting the Myxo device as only a minor modification of the previous device, Geoform Model 4200.

Meanwhile Dr. McCarthy of Northwestern Memorial Hospital tested the Myxo device during its clinical trial between 2006 and 2007. Despite this, the manufacturer neglected to tell the FDA that a new device was tested for the first time in humans. In addition, Northwestern and McCarthy neglected to tell the patients using full informed consent, as stated to the Senate Finance Committee in 2010. This human experiment was unlawfully done without informed consent and without FDA knowledge, despite Dr. Nalini Rajamannan the Valve Director at Northwestern University attempts to bring the human clinical trial to the attention of Northwestern University Dean's office and the Board of Trustees, the FDA, Health and Human Services(HHS) and the National Institute of Health(NIH). In October 2008, FDA initiated a voluntary recall pursuant to 21CFR7 and cleared the device with a new name in April 2009.

On July 16, 2009, the congressional liaison from the FDA wrote a letter to patient Antonista Vlahoulis deeming the Myxo device investigational. The letter also stated Senator Richard Durbin would contact her regarding the investigational status. Vlahoulis claims to not have received any form of contact from the Illinois Senator

to date. When recently contacted, Senator Durbin's office failed to comment on the issue.

In 2008, Senator Charles Grassley of Iowa initiated a Senate Finance Investigation by sending several Congressional letters to Northwestern, Edwards and the FDA. This investigation appears to have gone stagnant since 2010, the last time in which any updated information was released.

When contacted, Senator Grassley's aid mentioned that "competing interests" are preventing them from commenting.

The fact that a company could invent a new device then test it for the first time in humans without telling anyone raises questions. The FDA admits that Edwards marketed the device without the necessary 510k clearance. Despite this, they still cleared the predicate device the dETlogix model 5100 and a second device, the IMR model 4100.

How can a company manufacture and market a device without registering the device with the FDA, and then market the device in the United States by following Security Exchange Commission(SEC) guidelines? In order for this to happen, the device needs to be on a 510(k) exempt list.

According to the FDA "Edwards Lifesciences did not seek 510(k) clearance prior to marketing since they didn't think the product had changed enough for a new clearance. FDA disagreed, and the company submitted a 510(k) application for dETlogix, which was cleared by FDA." "510(k) (premarket notification) to FDA is required at least 90 days before marketing unless the device is exempt from 510(k) requirements in 21 CFR 807." However, the devices that are exempt from 510(k) are listed in the following table from the FDA website, of note annuloplasty devices are not on this exempt list.

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