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United States Senate

COMMITTEE ON THE JUDICIARY

WASHINGTON, DC 20510-6275

March 4, 2014

VIA ELECTRONIC TRANSMISSION

Morton Schapiro
President
Northwestern University
633 Clark Street
Evanston, IL 60208

Richard J. Gannotta
President
Northwestern Memorial Hospital
251 East Huron Street
Chicago, IL 60611

Dear Mr. Schapiro and Mr. Gannotta:

On December 3, 2008, and September 30, 2009, I wrote to you about troubling allegations that the Myxo-ETlogix 5100 Ring (Myxo Ring), an annuloplasty ring used in heart valve repair, had not been cleared for marketing by the Food and Drug Administration (FDA) before it was implanted in patients as part of an outcomes study.¹ In April 2009, the device was cleared with a new name, dETlogix Annuloplasty Ring.

Since we last corresponded, several inadequacies in the responses I received from the Northwestern entities² have been brought to my attention. First, it appears that Dr. Patrick McCarthy made contradictory statements regarding the similarity of the Myxo Ring to preexisting devices. Second, it is not clear whether patients received sufficient notice of the safety questions that arose regarding the Mxyo Ring implanted at Northwestern Memorial Hospital (NMH).

Most alarmingly, however, I recently received a report from Dr. Nalini Rajamannan – a former professor and physician at Northwestern University’s Feinberg School of Medicine and co-author of the protocol for the study – alleging that a series of documents that fall squarely within the scope of my December 3, 2008 letter was withheld by the University, without any notice that the documents were being withheld.

Specifically, the withheld documents pertain to IRB Project Number 1532-004 and consist of the following:

- (1) A Protocol Application signed by Dr. Patrick McCarthy;
- (2) An Echo Protocol entitled, “Mitral Valve Pathology: A Quantitative Assessment Pre- and Post- Repair,” authored by Dr. McCarthy;

¹ “Early and Late Outcomes Following Surgical Intervention for Atrial Fibrillation Database.”

² Northwestern University (University); Northwestern Memorial Hospital (NMH); and Northwestern Memorial Faculty Foundation (NMFF).

- (3) A Waiver of Consent Form signed by Dr. McCarthy;
- (4) A cover letter dated June 29, 2006 and addressed to Dr. McCarthy from Eileen Yates of the University's IRB, which approved IRB Project Number 1532-004 for the period 6/29/2006-6/27/2007 under submission accession number 200606-0680; and
- (5) A HIPAA Waiver of Authorization Form attached to a cover letter dated June 29, 2006 and addressed to Dr. McCarthy from Eileen Yates of the University's IRB.

Moreover, it is alleged that each of these documents were either signed or submitted by Dr. McCarthy in June 2006. If these allegations are true, each of these documents should have been produced in response to Question 2 of my December 3, 2008 letter, which requested:

Please provide a copy of all internal communications and correspondence regarding the Myxo Ring and the use of the device as part of an outcomes study. This request covers the period of January 2006 through the date of this letter.

As part of its January 5, 2009 response, the University produced a number of documents pertaining to IRB Project Number 1532-003 which were held out as responsive – including a New Project Submission Form (NPSF),⁶ a Waiver of Consent Form,⁷ and a HIPPA Waiver of Authorization Form.⁸ If other responsive documents were to be withheld, then notice and an explanation of the reasons for withholding them should have been provided.

To address this inadequacy in your previous document productions, please respond to the following requests for information:

- (1) Please provide a copy of the following documents pertaining to IRB Project Number 1532-004:
 - a. A Protocol Application signed by Dr. Patrick McCarthy;
 - b. An Echo Protocol entitled, "Mitral Valve Pathology: A Quantitative Assessment Pre- and Post- Repair," authored by Dr. McCarthy;
 - c. A Waiver of Consent Form signed by Dr. McCarthy;
 - d. A cover letter dated June 29, 2006 and addressed to Dr. McCarthy from Eileen Yates of the University's IRB, which approved IRB Project Number 1532-004 for the period 6/29/2006-6/27/2007 under submission accession number 200606-0680; and

⁶ NWU 00042 – NWU 00058.

⁷ NWU 00059 – NWU 00060.

⁸ NWU 00061 – NWU 00065.

e. A HIPAA Waiver of Authorization Form attached to a cover letter dated June 29, 2006 and addressed to Dr. McCarthy from Eileen Yates of the University's IRB.

(2) Please provide a copy of any other documentation, form, report, email, or memorandum regarding IRB Project Number 1532-004, including a New Project Submission Form, that is in the possession of the University, NMH, or NMFF. This request covers the period of January 2005 through the date of this letter.

Thank you for your cooperation in this matter. I would appreciate a response by March 14, 2014. Should you have any questions, please contact Jay Lim of my Committee staff at (202) 224-5225.

Sincerely,



Charles E. Grassley
Ranking Member
Committee on the Judiciary