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David S. Rosenbloom
Attorney at Law
[redacted]

October 30, 2009

VIA E-MAIL AND FED-EX

The Honorable Charles Grassley, Ranking Member
Committee on Finance
SD 219
135 Hart Senate Office
Washington DC 20510
ATTN: Mr. Brian Downey
Brian.Downey@finance-rep.senate.gov

Re: Letter of September 30, 2009 to Northwestern Memorial Healthcare

Dear Senator Grassley:

I am writing again on behalf of Northwestern Memorial Hospital ("NMH") to summarize the efforts of NMH and the Northwestern Medical Faculty Foundation ("NMFF") to identify information and documents responsive to the additional questions raised in your letter of September 30, 2009. We understand that Northwestern University, the other recipient of your letter, will be providing a separate response.

As we have previously noted, we are producing our responses pursuant to Senate Rule XXIX and request that you treat this information as Committee Confidential under that Senate Rule. Because we are providing information pursuant to a Congressional demand letter, we understand that we waive no otherwise applicable privileges that exist under state or federal law.

Because your letter raises various questions about the FDA regulatory approval process for a medical device that was implanted in patients at NMH, we thought it important to reiterate at the outset the differing roles and responsibilities that health care providers and device manufacturers play in providing patients access to safe and effective medical devices that treat serious medical conditions. As you would expect, health care providers, such as the physicians who serve on the staff of NMH, take seriously their responsibility to be knowledgeable in the latest diagnostic and treatment techniques, and to be aware of the vast spectrum of drugs and devices that are commercially available to provide beneficial therapies to patients. What health care providers cannot reasonably do, however, is to second guess the decisions of manufacturers to distribute products as approved medical devices, or the decisions of the regulators to allow such distribution. To the contrary, health care providers necessarily rely on medical device, equipment, and product manufacturers, pharmaceutical companies, and the government agencies that regulate those entities, to ensure that manufacturers provide safe and compliant products to

patients. Neither hospitals nor physicians have the technological ability or regulatory expertise to address whether a medical device has been properly cleared for market pursuant to the FDA's regulatory processes. Moreover, neither the FDA nor any other regulatory body has ever placed a separate obligation on the user of a medical device to verify that proper steps were taken to clear a device for market.

Manufacturers, on the other hand, necessarily develop extensive expertise in the regulations and guidance issued by the FDA relating to the clearing of medical devices for marketing. This repository of expertise at the manufacturer level reflects the reality that all constituencies, including both the FDA and the health care provider community, look to manufacturers to ensure that all regulatory hurdles are cleared before drugs or medical devices are brought to market. Thus, the practical reality is that the commercial distribution of a medical device to physicians and hospitals is a representation by the manufacturer that the device is being legally marketed under applicable laws and regulations, and that the device is safe for use in patient care.

In contrast to the commercial marketing of a cleared device, there are well established, and carefully controlled, regulatory pathways by which manufacturers can distribute devices that are not yet cleared. For example, if a device is not yet cleared for sale, the manufacturer must inform the hospitals and physicians to whom it offers to make the devices available that the device is investigational. The manufacturer and the provider can then discuss whether the provider would like to participate in a clinical trial or some other investigation of the device. If the provider is interested in investigational use of the device, the provider will then make arrangements with an institutional review board (IRB) before using the device in a clinical trial or in an investigational setting.

The common denominator between the approved commercial distribution of a device and the investigational distribution of a device, is that the device manufacturer is necessarily the source of all information regarding any restrictions on the use of the device. In both scenarios, the health care provider relies on the manufacturer to provide timely and accurate information regarding the regulatory status of the device.

With this general background in mind, we proceed to address the specific questions of your September 30 letter:

1. **Did Dr. McCarthy, Northwestern and/or the Hospital request confirmation from the company that the Myxo ETlogix 5100 Ring was cleared by the FDA before Dr. McCarthy first implanted the device? If so, on what date was the request(s) made, by whom, to whom at Edwards, and on what date was the assurance(s) received?**

   Northwestern Memorial Hospital did not request additional confirmation from the manufacturer that the Myxo Ring was cleared by the FDA before Dr. Patrick McCarthy first implanted it. Dr. McCarthy and NMH rely upon manufacturers to comply with all applicable regulatory requirements. Edwards Lifesciences LLC ("Edwards") is a well-established manufacturer of heart valves and related products. As such, Edwards has a non-delegable duty of ensuring regulatory compliance for all its products. Edwards

provided the Myxo ETlogix 5100 Ring (the "Myxo Ring") to NMH in commercial packaging, with a commercial label, as is the case with any other lawful device approved by the FDA or cleared for market through the FDA's process. When the Myxo Ring was first used at NMH, we understood that Edwards had fully complied with any and all FDA regulations that would allow the marketing of the product, and at no time did Edwards suggest that the device was investigational.

In order to respond completely to your inquiry, we have inquired of Dr. McCarthy about his communications with Edwards, both in his capacity as a clinician practicing at NMH and in his consulting role to Edwards. Dr. McCarthy again confirmed that he did not participate in the regulatory decision-making process at Edwards related to clearing the Myxo Ring for market. To the contrary, Dr. McCarthy has assured us that at no time did Edwards directly or indirectly inform him that the Myxo Ring would be considered an experimental or investigational device. In fact, Edwards assured Dr. McCarthy that it was taking the steps necessary to obtain FDA approval. For example, in October 2005, over five months before Dr. McCarthy first used the Myxo Ring, one of Edwards' engineers informed Dr. McCarthy that Edwards was in the process of ordering rings needed to complete its in-house testing, which was required for FDA approval. (A copy of the email dated October 21, 2005, is enclosed herewith.) While Dr. McCarthy had no knowledge of what particular testing was required by the FDA, or to which test this email referred, this type of communication confirmed his understanding that Edwards was doing whatever was necessary to comply with applicable FDA guidelines, whatever those might be.

Heart valve surgery, in particular valve repair, is one of Dr. McCarthy's areas of expertise, and he is a leader in the field of heart valve repair. Given his level of expertise and depth of experience, it is not surprising that Dr. McCarthy has invented several concepts used in the heart valve repair field, including the technology that resulted in the Myxo Ring, which was the third heart valve repair ring he created and assisted in developing for Edwards. As described above, it is our understanding that Dr. McCarthy's relationship with Edwards is based entirely on Dr. McCarthy's nationally recognized clinical expertise, and not at all on any notion that Dr. McCarthy had or has any regulatory expertise. Consistent with this purely clinical focus, during the time Dr. McCarthy worked with Edwards in developing and finalizing the design for the Myxo Ring, his communications with Edwards dealt almost exclusively with the ring's design, engineering and other scientific aspects. The only exception to these purely clinical communications that Dr. McCarthy reports was that Edwards also occasionally sought Dr. McCarthy's input concerning marketing materials for the Myxo Ring, which again reflects Edwards interest in Dr. McCarthy's clinical understandings of the circumstances in which the ring would be considered for use by other clinical providers. Such marketing communications do not suggest any role for Dr. McCarthy in the regulatory approval process.

2. **Please provide the Committee with a copy of emails, letters, memoranda, or any other documentation of Edwards' assurance to Dr. McCarthy, Northwestern, and the Hospital that the Myxo ETlogix 5100 Ring was cleared by the FDA prior to use in the cardiac surgery outcomes registry. This request covers the period of August 1, 2005 through April 30, 2006.**

   Other than the previously referenced commercial packaging and labeling and for the time period specified above, there are no emails, letters, memoranda or documentation of Edwards' assurances to NMH that the Myxo Ring was cleared by the FDA. Edwards did, however, send an email in October of 2005 to Dr. McCarthy, confirming that Edwards was conducting in-house testing pursuant to the FDA process for device clearance. Please see answer to Question One regarding the 2005 email and the process established by the FDA. Pursuant to that process, the device manufacturer is vested with the responsibility to clear a device for market.

   When a question was raised as to proper clearance, Edwards supplied confirmation emails on August 28, 2007 and September 10, 2007, and these were produced in our correspondence to Senator Grassley dated January 16, 2009.

3. **If written assurance or confirmation was not requested and/or provided, please explain why not and on what basis Dr. McCarthy, the Hospital and/or Northwestern that the device had been cleared for use.**

   In 2006, when Edwards first marketed the Myxo Ring, NMH and Dr. McCarthy considered the distribution of the device with commercial packaging and labeling as a representation by Edwards that the ring was safe and compliant with all FDA regulations. With no information to the contrary, neither NMH nor Dr. McCarthy sought additional assurances. Indeed, it was not an industry standard for physicians, hospitals or other purchasing entities to conduct a review of the regulatory compliance of medical devices being marketed by medical device manufacturers for commercial use. In fact, as discussed above, it is our understanding that the regulations established by the FDA vest the device manufacturer with the responsibility to ensure that a device is safe and properly cleared for market. Further answering, please refer to answers to Questions One and Two.

4. **The Hospital stated, "At no time did any surgeon at the Hospital believe themselves to be implanting an investigational or experimental device." Other than Dr. McCarthy, how many other surgeons at the Hospital implanted the device during the period between March 1, 2006 and August 30, 2007? Did any of these surgeons inquire about the approval status of the device before they first used the device? If not, on what basis did they determine that they were implanting a cleared device?**

   Because of his national prominence and expertise in the specialized area of myxomatous valve repair, Dr. McCarthy performed the great majority of the myxomatous valve repair surgeries at NMH. One other attending surgeon at NMH implanted the Myxo Ring

between March 1, 2006 and August 30, 2007. That surgeon implanted the device with the understanding described above, that the act of labeling and selling the product commercially, was a representation by Edwards that the product was marketed in compliance with all applicable FDA regulations. The surgeon did not inquire further about the approval status of the device. Further answering, please see answers to Questions One, Two, and Three.

5. **What policies and protocols do Northwestern and the Hospital have in place to ensure that the appropriate assurances are obtained regarding the status of a device before it is first used by a faculty member and/or Hospital physician?**

Northwestern Memorial Hospital has formed a Medical Device Executive Committee that first convened in October of 2007. The Committee receives all new medical device/product requests. As part of the process, the Committee confirms that a new product has been approved by the FDA or cleared for market through an FDA process. The Committee continues to rely on the information it receives from the medical device manufacturer regarding FDA approval. The Committee does not question or conduct a review of the process that was used to obtain FDA approval or clearance.

6. **What policies and protocols do Northwestern and the Hospital have in place to respond to instances where the university and/or the hospital realize after the fact that a device being used in the hospital for treatment or research has not been appropriately cleared by the FDA? How many times has such an occurrence taken place in the last 5 years? What measures were taken by Northwestern and/or the Hospital to address the matter? Were the patients subsequently informed or re-consented? If not, why not?**

Northwestern Memorial Hospital has no written policy or protocol in place to respond to instances where it realizes after the fact that a device being used in the hospital has not been appropriately cleared by the FDA. Such an occurrence has never taken place in the last five years.

To be clear, NMH has neither the regulatory expertise, nor a sufficient first-hand knowledge of all the relevant facts, to express a definitive opinion as to the merits of the various positions asserted by the FDA and Edwards during their resolution of the issues related to the Myxo Ring. Northwestern Memorial Hospital understands that Edwards originally believed and asserted that it cleared the Myxo Ring through the FDA's guidance document of January 10, 1997, "Deciding When to Submit a 510(k) for a Change to an Existing Device," because Edwards concluded that the ring was a minor modification of a device previously cleared through the 510(k) process. Edwards also determined that a separate 510(k) premarket notification was not required. We, of course, are also aware that questions later arose as to whether Edwards correctly interpreted or applied the FDA's guidance document. We have no personal knowledge of the discussions between Edwards and the FDA on this subject. While it appears to us

from published reports and subsequent events that this issue was appropriately resolved between the FDA and Edwards, it is undisputed that neither NMH nor Dr. McCarthy had any part in that resolution process. In any event, when Edwards later submitted a 510(k) premarket notification for the ring, the FDA approved the ring for commercial distribution to market without requiring any changes to the ring.

Despite the affirmative evidence of the ring's safety and efficacy, in light of the publicized issues regarding the ring and to address any patient concern, Northwestern Memorial Hospital issued two letters to patients who received the ring (a copy of each is enclosed). The first letter explained that Edwards voluntarily took the ring off the market pending the FDA's decision. The second letter explained that the FDA had cleared the ring for market without making a single change to the ring. Both letters reiterated NMH's unequivocal belief that the Myxo Ring was safe and effective. Northwestern Memorial Hospital also set up a phone line to answer any questions that patients had.

In conclusion, NMH appreciates this opportunity to respond to Senator Grassley's questions regarding the circumstances surrounding its use of this important and safe medical device. Northwestern Memorial Hospital is committed to high quality, safe patient care, as demonstrated by national awards in quality health care and its reporting of more than 300 quality measures on its website. Dr. McCarthy's very motivation in creating the Myxo Ring was to aid heart surgeons everywhere in hopes of offering a better alternative to patients with diseased valves who might otherwise face a lifetime of beta blockers or blood thinners. We hope that it is clear to you that neither NMH nor Dr. McCarthy would risk patient safety (or their hard-earned reputations) by giving patients devices that were not legally marketed.

In health care generally and academic medicine in particular, there is an ever-evolving landscape of laws, regulations, guidelines, and best practices. Northwestern Memorial Hospital is part of an academic medical center that prides itself on not only being compliant with the law, but on maintaining best practices in the industry. Northwestern Memorial Hospital's and Dr. McCarthy's reliance on Edwards' representations that the Myxo Ring was a properly approved and legally marketed device in 2006 was reasonable and well within industry standards. It would be patently unfair to health care providers to suggest that they must be policing manufacturers. Northwestern Memorial Hospital will continue to look at new ways to ensure the delivery of safe patient care, but it looks to the FDA and medical device manufacturers to do their part to ensure the delivery of safe medical devices that comport with all FDA regulations.

Sincerely,

David S. Rosenbloom

DSR/rw
Enclosure
[redacted]

-----Original Message-----
From: [redacted]
Sent: Friday, October 21, 2005 7:19 PM
To: [redacted]
Cc: [redacted]
Subject: Myxomatous Ring Comparison

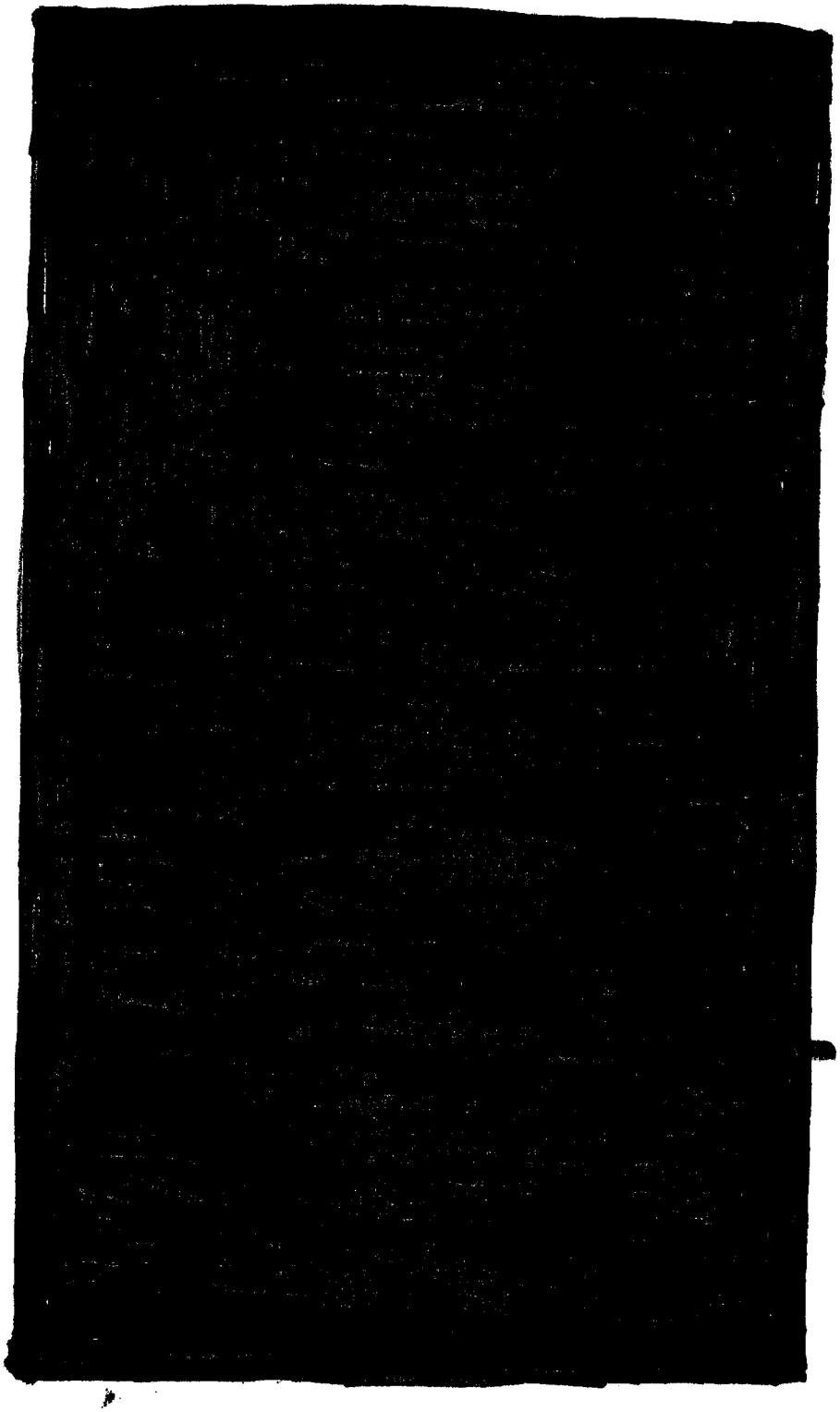
Dr. McCarthy,

Thank you very much for meeting with us last week. We appreciate the additional input and feel confident in finalizing the ring design. We are continuing to do our best to make product available to you as soon as possible and are in the process of ordering the rings needed to complete our in-houses testing, which is required for FDA approval. We will keep you updated on our progress.

As you requested, I am enclosing a comparison of the Myxomatous ring versus the Physio ring. Please let me know if you have any questions.

(See attached file: Myx_Physio Comparison.pdf)

Sincerely,
Vaso Adzich



January 26, 2009

Dear:

You may have seen some recent media reports regarding the Myxo ET Logix 5100 Annuloplasty Ring which you received during your heart surgery at Northwestern Memorial Hospital. I would like to provide you with some perspective regarding this ring and a contact here at Northwestern Memorial should you have additional questions or concerns.

Your surgeon, Patrick M. McCarthy, MD, chief, Division of Cardiothoracic Surgery, co-director of the Bluhm Cardiovascular Institute of Northwestern Memorial Hospital and Heller-Sacks Professor of Surgery at Northwestern University's Feinberg School of Medicine, is a co-inventor of this ring. As you are probably aware, Dr. McCarthy is a world-renowned cardiothoracic surgeon. He has published more than 300 papers and two books on matters related to the heart and heart failure.

Some news stories have reported allegations that the Myxo ET Logix 5100 ring was experimental and not cleared by the FDA for use. We do not consider this device to be experimental. We have relied upon the manufacturer, Edwards Lifesciences, to follow proper regulatory process to clear the device for market and we have been assured by Edwards that it did so. We believe it is safe and effective with very good results.

I hope this letter finds you well. Our organization-wide goal is to provide the *Best Patient Experience* for each patient and our dedicated staff works hard to ensure that we do so. Please feel free to contact [redacted] or [redacted] at [redacted] with any questions you may have regarding the ring or your procedure.

Sincerely,

[redacted]

[redacted]

May 8, 2009

Patient Name
Patient Address
Patient Address

Dear,

I am pleased to provide you with an update to my January 26, 2009 letter regarding the Myxo ET Logix 5100 Annuloplasty Ring, which you received during your heart surgery at Northwestern Memorial Hospital.

As I explained in my prior letter, Edwards Lifesciences, the ring's manufacturer, had assured us that the ring had gone through the appropriate process for clearance by the Food and Drug Administration (FDA) before making it commercially available. Last fall, Edwards voluntarily submitted the ring for another FDA review process. On April 10, 2009, after its review was complete, the FDA determined that the ring is safe and effective. This notice by the FDA officially permits Edwards to once again market the ring. Other than changing the name of the ring to Edwards dETLogix annuloplasty ring 5100, nothing else about it is different.

Your surgeon, Patrick M. McCarthy, MD, chief, Division of Cardiothoracic Surgery, co-director of the Bluhm Cardiovascular Institute of Northwestern Memorial Hospital and Heller-Sacks Professor of Surgery at Northwestern University's Feinberg School of Medicine, is a co-inventor of this ring. As an innovator and widely acclaimed cardiothoracic surgeon, Dr. McCarthy's contributions to advancing treatment options for patients with heart disease have been significant.

We are pleased with the FDA's confirmation and hope this information provides you with additional comfort and confidence about the care you received at Northwestern Memorial. Please feel free to contact [redacted] or [redacted] at [redacted] with any questions you may have regarding the ring or your procedure.

Sincerely,

[redacted]