Sheldon and Marion Davis Pacemaker Recycling World Headquarters Dedication at World Medical Relief

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Prepared Remarks

Doctor Samson, The Board of World Medical Relief, dear friends and supporters of WMR:

Today indeed is a historic day. We are celebrating a landmark achievement - the establishment of *first* institutional pacemaker re-cycling center.

The Center is the result of the shared vision of Dr. Kim Eagle and Mr. Sheldon Davis. It is the fruit of labor of countless volunteers. It is a paragon of the best in humanity - compassion and charity. It is what happens when people of good will come together to **build** something greater than themselves.

Pacing is widely available in the United States and other high income countries.

We take it for granted that when a patient is lightheaded or passes out, and is

diagnosed with complete heart block, he or she will walk out of the hospital with a pacemaker, and will be able to maintain the level of activity as before pacemaker implantation.

That is not the case in most of the world...That is not the case in most of the world.

Today, six decades after the pacemaker introduction into clinical medicine, as many as one million people still die each year due to a profoundly slow heart rate, one that is so slow, that it cannot sustain life. People die on *every* continent *every* day, because pacemaker therapy is *not* available. Nowhere is the access to pacemakers as scarce as in Africa. One third of African countries do not have a *single* hospital which can implant pacemakers.

One of those countries is Sierra Leone, a county of almost 8 million people. This February our team working together with Pace4Life, - United Kingdom sister charity of My Heart Your Heart, travelled to Sierra Leone to perform the first pacemaker implantation ever in that nation's history. We implanted 8 pacemakers within a week's stay. We helped **build** the first and only pacemaker implantation center there. Since our return, the country's only cardiologist has implanted several additional re-furbished pacemakers on his own. All patients did well and are doing well.

None of this would have been possible without the generosity of Marion and Davis Sheldon, or the vision of Dr. Kim Eagle. This vision is much broader than merely supplying pacemakers to the needy today. We are **building** the edifice of knowledge and experience to be shared with all who wish to follow us in our footsteps. We are creating the framework for large scale pacemaker reuse. We are systematically addressing key issues surrounding pacemaker reuse.

We began by surveying funeral home directors, and learning of their strong support for the concept. We surveyed patients in our pacemaker clinic at the University of Michigan to find out how they felt about the donating their pacemakers after death. Over 85% of folks thought they wanted to do that. They wanted to give a new chance for life to another human being.

We also found that a vast majority of Heart Rhythm specialists felt the practice of pacemaker reuse should be embraced. We examined the legal and regulatory environment. Pacemakers are approved as single use devices. We asked ourselves the question: is it ethical for us to offer indigent patients in poor countries pacemakers which we are not allowed to re-implant in the United States. Everything about this process has been systematic, pragmatic,

and transparent. Everything we did has been challenged. Everything we did has withstood the peer review process.

Most of all we sought partnerships. World Medical Relief is our most essential and precious partner. Thanks to the generosity and the vision of Dr. Samson and the WMR board of directors we were offered this beautiful and substantial space, which we celebrate today.

My colleague and dear friend, Doctor Timir Baman who co-founded project My Heart Your Heart with Eagle also found Mr. Brad Wasserman and his company Implant Recycling then of Detroit, now of Sterling Heights. We have benefited from Implant Recycling tremendously as they embraced our work, brought us tens of thousands of pacemakers to evaluate, and contributed financially.

Much of our effort was focused on developing protocols for proper cleaning, electrical testing, and sterilization of pacemakers. This effort lead to My Heart Your Heart obtaining US FDA approval for pacemaker export. This result would not have been possible without Mr. Craig Allmendinger and his company, called NEScientific, which is based in CT, which clans and sterilized our pacemakers free of charge. This achievement would also not have been possible without Mr. Noah Klugman who at the time was a graduate student at the University of

Michigan in the department of electrical engineering and computer science, and who has built the electrical testing equipment which we use today.

We now have an approval of the University of Michigan ethics board, to perform the definitive trial to provide the proof of the highest quality that reusing pacemakers is safe and effective. The study will start this Summer in several countries spanning South America, Africa, and Asia. I know that the clinical study will demonstrate, what we already know is true, that reusing pacemakers should be done to save lives of those who cannot access this therapy in low income countries.

While pacemaker recycling has been carried out on a small scale for many years by individuals, it is My Heart Your Heart which is creating the standard for pacemaker reprocessing and reuse. With everything we do, with each step we take, we are purposely leaving a trail of literature behind. This way the knowledge and experience of how to recycle pacemakers will outlive this space. The knowledge and experience will outlive all of us. It will be there for future generations.

Despite the real risk of omitting someone who helped a lot, in addition to the individuals I acknowledged earlier, I feel I must mention by name additional key

individuals, without whose generosity of heart, steadfastness, dedication, and voluntarism we would not be here today.

I want to thank Ms. Eva Kline-Rogers and Mr. Bruce Rogers, Mr. Eric Puroll, and Ms. Patsy Bruenger, all from the Michigan Clinical Outcomes Research and Reporting Program

I wish to thank Mr. Kevin Weatherwax from Michigan Institute for Clinical and Health Research

So much work has been done by United 2 Heal and their technical team represented here today by Ms. Allyson Wittsett and Mr. Jad Baki

Finally, I wish to acknowledge pacemaker nurses from the University of Michigan Cardiovascular Center:

Mr. Dan Bochinski

Ms. Anne Donatto

Ms. Sharon Gadoth-Goodman

Ms. Ashley McFarland

Ms. Helen Mcfarland

Ms. Michelle Nichols

Mr Ross Sample

Ms. Pat Sovitch

Each and every one of you made it possible for us to get to this point, you all have contributed to today's success. With you and thanks to you, this program will endure.

Thank you all very much.