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Submitted to the Medicare Coverage Advisory Committee, in advance of the March 12, 2003 hearing on coverage for Left Ventricular Assist Devices as "Destination Therapy"

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Good morning. I am William Baumgartner, M.D., Vincent Gott Professor and Cardiac Surgeon-in-Charge at the Johns Hopkins Medical Institutions, and immediate past President of the Society of Thoracic Surgeons. I am speaking here on behalf of both the Society of Thoracic Surgeons and the American Association for Thoracic Surgery. These two organizations represent essentially all practicing cardiothoracic surgeons in the United States, as well as cardiothoracic surgeons throughout the world.

I have no financial interest in the companies presenting here today, nor in any of their competitors. Although I am a heart transplant surgeon, neither I nor my institution (Johns Hopkins Hospital) participated in the REMATCH trial.

The last thirty years have seen remarkable advances in the diagnosis and treatment of heart disease. Cardiologists can image the heart non invasively, making diagnoses that allow for early treatment of disease with medication or interventional procedures. In patients with more advanced disease, cardiothoracic surgeons such as myself routinely perform coronary artery bypass surgery and repair or replace heart valves. These advances have transformed medicine and saved or prolonged the lives of millions of Americans. There remains, however, a devastating heart disorder that affects and

shortens the lives of millions more. The treatment of Congestive Heart Failure, which now accounts for more than 250,000 deaths a year, remains one of our most difficult challenges.

With the development of effective immuno-suppression to prevent transplant rejection – techniques pioneered by Dr. Norman Shumway at Stanford, among others -- heart transplantation has now become a viable therapy for many of these patients. There is, unfortunately, a cohort of patients who are not, for various reasons, candidates for transplantation. Medical therapy has provided some, but limited, benefit in prolonging life in these patients.

We have carefully studied the results of the REMATCH trial. We believe the evidence clearly supports the use of Left Ventricular Assist Devices for treatment of heart failure in patients meeting the selection criteria outlined in the trial. The one-year survival data demonstrates a two-fold survival advantage over medical treatment alone at one year as well as marked improvement in quality of life. Certainly, challenging issues remain, particularly in the medical management of patients after implantation of a VAD. However, our past experience with evolving technologies, such as cardiac revascularization and heart transplantation, leads us to believe that both outcomes and quality of life will continue to improve as surgeons, cardiologists, and the supporting healthcare personnel gain further experience with this technology.

I do not want to take your time with detailed analysis of the REMATCH data, as that would duplicate what you have already heard. Instead, let me discuss other issues, such as diffusion of this technology, criteria for qualifying centers and physicians, and the development of a database for quality improvement.

First, we support the recommendations of the International Society of Heart and Lung Transplantation regarding criteria. We agree that dissemination of this technology should be rational and controlled. The patient selection criteria for the REMATCH trial were precise and should be followed. This technology should be reserved for patients for whom a transplant is not appropriate, but who have a sufficient life expectancy, that with a ventricular assist device, they will benefit, both in duration and quality of life. Inappropriate utilization of this technology in patients eligible for transplant or in those with multiple medical contradictions would be a grave error, both medically and morally. Proper patient selection is essential. We in the medical community must take steps to ensure that this technology be applied only to those patients in whom significant benefit is likely to be achieved.

One option would be to reserve use of VADs for destination therapy either to centers that participated in the REMATCH trial or to centers now approved for heart transplantation. We believe this would be overly restrictive, as it would in practice deny this therapy to patients who do not have access to REMATCH participants or to transplant centers. Despite our best intentions and efforts, this would likely discriminate against many patients as a result of geographic and/or socioeconomic limitations. How can we

responsibly expand access while assuring that patient selection and perioperative management remain not just at acceptable but rather at optimal levels?

We suggest that Medicare approval of centers for implantation of LVADs be phased in, depending on proven experience and qualifications of centers and of medical staff. REMATCH participants should be qualified immediately. Heart transplant centers with experience in use of LVADs as a bridge to transplantation should be qualified as soon as they demonstrate that their medical staff have expertise in the selection of appropriate patients for destination therapy and in the longer-term medical management of their patients receiving LVADs. Additional training required for the medical staff of existing transplant centers, who do not at present demonstrate this expertise, should be made available immediately at the REMATCH institutions or other centers experienced in the use of LVADs that subsequently qualify for use of VADs as destination therapy.

Other medical centers desiring to offer this therapy should be required to meet more restrictive criteria before being approved for Medicare coverage. The cardiologists, cardiothoracic surgeons, and other medical personnel should be trained in this technology either at the REMATCH institutions or at the transplant centers that are able to build upon their present experience with LVADs as the bridge to transplantation. The pool of physicians qualified to offer this treatment would grow naturally as trainees at transplant centers providing destination VAD therapy complete their training and disperse to other institutions. In addition, there should be the opportunity for those practicing heart specialists who wish to acquire the skills necessary for the delivery of this advanced care

to do so. They would need to undergo additional training by the qualified centers, prior to offering this therapy. Although diffusion of this technology will inevitably occur slowly, such systematic and deliberate efforts will be essential to ensure appropriate patient selection and the highest quality patient care.

Second, we believe that there should be established criteria for the experience and qualifications thoracic surgeons and other medical staff must meet before institutions beyond the REMATCH participants and transplant centers qualify to offer this technology. While this will require cooperative effort, it is eminently doable. One precedent for this type of effort is the requirement for certification by the United Network for Organ Sharing (UNOS). As you know this organization is responsible for overseeing transplantation in this country and has established, with the help of specialty societies such as ours, criteria for clinical experience in transplant care by cardiologists, surgeons and institutions alike. We have had experience in assisting practitioners in implementing new surgical technology in the past. Following the advent of video-endoscopy, which led to the very successful technique of laparoscopic cholecystectomy in the late 1980s, video-thoracoscopy soon emerged as new technology for treating intrathoracic disease. Video-thoracoscopy rapidly became associated with smaller chest incisions, less pain and shorter hospitalization, all of which met with rapid patient approval and reduced hospital cost. Because thoracic surgeons at that time had little experience with endoscopic techniques, the STS in 1990 convened a taskforce to evaluate this new technology. The specific charge was to define the scope of practice, develop a methodology to train thoracic surgeons who were already in practice, and establish criteria by which this

technology, which became known as Video-Assisted Thoracic Surgery (VATS), could be successfully introduced into hospitals. Multiple wet-laboratory courses sponsored by the STS were offered throughout the United States where thoracic surgeon attendees were introduced to the technology and required to perform specific intrathoracic operations. Following successful course completion, attendees were subsequently required to perform a specified number of procedures at their home hospital, under experienced supervision, before VATS could be added to the armamentarium of that hospital. As a critical mass of trained thoracic surgeons became available, VATS was eventually introduced as an integral part of thoracic surgery residency. The end-result is that today all thoracic residents are trained in video-thoracosopy. In 1992, mission accomplished, the wet-laboratory courses were discontinued by the STS.

In the case of VADs for destination therapy, the training and experience criteria will be more complex, encompassing patient selection and subsequent medical management as well as surgical technique. We in the thoracic surgical community recognize our responsibility and are ready to offer the resources of our societies to CMS in the development of standards for training and in facilitating the certification of surgeons who wish to embrace this new technology for the betterment of their patients. We have already established workforces on the treatment of end-stage congestive heart failure and on clinical education. These workforces were designed to facilitate such training and certification processes and can provide immediate input from experts in ventricular assist utilization and in clinical education.

Finally, we believe that ongoing participation in a centralized clinical database must be a criterion for coverage. Especially in areas of evolving medical technology and practice, accurate information regarding patient characteristics and results will allow for ongoing refinements in patient selection, operative technique and perioperative management. Such quality improvement efforts serve not only the best interests of the patients but the medical community and society at large. We therefore would propose that every institution wishing certification for VAD implantation must be required to participate in a centralized clinical database. Demographic and clinical data regarding patient characteristics as well as information on hospitalization, adverse events and longterm outcome would be collected in accordance with HIPAA regulations so that patient confidentiality would be protected. Such information, when analyzed appropriately, would allow for continuous quality improvement and further refinement of eligibility requirements.

The precedent for such a database exists within our own thoracic surgical community. The adult cardiac surgical database of the Society of Thoracic Surgeons provides a model for clinical database development regarding the type of clinical data required from patients receiving LVADs as destination therapy. This database now provides data on over two million patients who have received coronary artery bypass surgery in the last 13 years. Risk algorithms have been developed that require reporting of defined parameters that affect the outcomes of CABG surgery, including co-morbid conditions, disease history, and other relevant factors. Information on outcomes is reviewed regularly by the participating hospitals and surgeons, enabling them to compare their own results with

regional and national results and thus determine when alterations in technical or operational processes are indicated. Identities are blinded so as to not discourage reporting, and each hospital or group knows how its own results compare with others, regionally and nationally. Despite the fact that we are now operating on older patients, with comorbidities that make good outcomes more difficult to achieve, mortality for these procedures has been reduced 23 percent in the last ten years. Similar criteria for reporting patient conditions and outcomes can readily be developed from the REMATCH patient selection criteria and will enable us to improve upon the already impressive results of the REMATCH trial.

In addition to patient characteristics, the STS cardiac database at present requires participants to report on length of hospital stay and adverse perioperative events, including hospital readmissions, within the standard 90-day surgical global period. Some further information specific to VAD patients will need to be collected to establish an optimal database. This would include data regarding longer term followup (two years), medical (vis a vis surgical) adverse events and quality of life measures. The STS is now consulting with the ISHLT on development of this database, which would be an extension of a patient registry already established by ISHLT. Such data collection and quality assurance programs will not be without cost; additional funding must be provided, either through the reimbursement process or another mechanism, to support these essential activities.

In summary, we believe that the REMATCH trial has conclusively demonstrated that LVADs are reasonable and effective in prolonging life, with satisfactory quality of life, for a small cohort of properly selected patients. The criteria utilized in the REMATCH trial should be utilized for Medicare coverage. Coverage should be limited to institutions that have staff with demonstrated competence in selection and management of these patients, beginning with REMATCH participants and established heart transplant centers. Training for physicians must be provided, and must be required, for further diffusion to other centers, so that appropriate patients are not denied treatment by geography or personal limitations. And finally, complete patient follow-up must be required, through a thorough and well-managed database so that effective efforts at refinement and quality improvement can be undertaken. The Society of Thoracic Surgeons and the American Association for Thoracic Surgery stand ready to assist CMS and the medical community as we move forward with this successful innovation in the medical and surgical management of advanced heart disease.