April 21, 2008

The Honorable Michael O. Leavitt
Secretary
United States Department of
Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Leavitt:

On behalf of the American Society of Transplant Surgeons (ASTS), American Society of Transplantation (AST), Association of Organ Procurement Organizations (AOPO), American Society of Multicultural Health and Transplant Professionals (ASMHTP), Cell Transplant Society (CTS), Diabetes Research Institute Foundation (DRIF), International Pancreas and Islet Transplant Association (IPITA), Juvenile Diabetes Research Foundation (JDRF), Principal Investigators of the NIH-sponsored Clinical Islet Transplant consortium, Principal Investigators of the NIH-sponsored Islet Cell Resource Centers, The Organization for Transplant Professionals (NATCO) and The Transplantation Society (TTS), we are writing to you to request a meeting to discuss the significant negative impact of Centers for Medicare and Medicaid Services (CMS) financial accounting and related policies on the future of islet transplantation research and the health of patients with Type I diabetes.

Islet transplantation is a very promising therapy for select patients with type 1 diabetes. Continued clinical investigation is required to define the long-term safety and efficacy outcomes before the procedure will be accepted as a standard of care even for those with the most severe manifestations of diabetes. Threatening successful accomplishment of these and other innovative studies designed to advance the field are the complex financial cost accounting issues that pose undue burden on organ procurement organizations and transplant centers trying to manage the costs of the pancreata from deceased donors needed to isolate islets. Compounding the problem is the recent ruling by CMS regarding "intent to transplant" (CMS-1543-R Dec. 21, 2006: Allocation of Donor Acquisition Costs Incurred by Organ Procurement Organizations) that does not account for the clinical need to complete the manufacturing process for islets before suitability and transplant intent of the pancreata involved can be determined.

These policies have contributed to the closure of numerous islet transplant programs over the past two years and are inconsistent with both Congressional intent to support islet transplantation research and with the objectives of other agencies within the Department of Health and Human Services (the "Department"), including the National Institutes of Health (NIH) and the Health Resources and Services Administration (HRSA).

The CMS policies at issue and their impact on islet transplant programs throughout the United States are addressed at length in the attached "White Paper," which has also been accepted for publication in a leading transplant journal in North America, the *American Journal of Transplantation*, and endorsed by the following societies and foundations:

American Society of Transplant Surgeons (ASTS)
American Society of Transplantation (AST)
Association of Organ Procurement Organizations (AOPO)
American Society of Multicultural Health and Transplant Professionals (ASMHTP)
Cell Transplant Society (CTS)

Diabetes Research Institute Foundation (DRIF)
International Pancreas and Islet Transplant Association (IPITA)
Juvenile Diabetes Research Foundation (JDRF)
Principal Investigators of the NIH-sponsored Clinical Islet Transplant Consortium
Principal Investigators of the NIH-sponsored Islet Cell Resource Centers
The Organization for Transplant Professionals (NATCO)
The Transplantation Society (TTS)

Cellular transplantation, including islet transplantation, has the potential to revolutionize treatment for a wide range of human diseases. However, islet transplantation is not yet considered accepted clinical practice. Its utility as a safe and efficacious therapy for type 1 diabetes will be determined over the next three to four years based on the results of an ongoing pivotal Phase III clinical trial in conjunction with FDA registration and funded through the NIH-sponsored Clinical Islet Transplantation (CIT) consortium.

Although islet transplantation is currently considered investigational and therefore ineligible for Medicare coverage under generally applicable Medicare coverage rules, Congress— intending to support research in this area— authorized Medicare coverage for islet transplants performed for certain Medicare beneficiaries participating in the NIH-funded CIT consortium. See Section 733(b) of Pub. L. 108-173. This clinical trial has just begun enrollment of patients; however, it is anticipated that the Medicare Program's financial exposure will be relatively limited, since the trial only requires that 65 Medicare patients receive islet transplants over the next three years— a small fraction of the thousands of type I diabetics that could potentially benefit from islet transplantation, should it prove to be a safe and effective therapy for the treatment of type I diabetes.

Ironically, rather that furthering islet transplantation research, as Congress intended, current CMS policy results in pancreases for islets using full organ costing and OPOs are thereby forced to establish organ charges to bear these costs. This has occurred due to the confluence of a number of CMS policies. First, in 2006, CMS issued a ruling on Medicare payment organs used in transplantation (CMS 1541-R) (December 21, 2006) (the "Ruling"), which requires OPOs to allocate substantial organ procurement costs if an organ procurement team "intends" to procure an organ for transplantation—regardless of whether the organ is actually surgically procured from the deceased donor and ultimately transplanted. While the "intent to transplant" can be reasonably determined in advance of the actual surgical procurement for whole organ transplants, "intent to transplant" for islet transplants cannot be determined until after the surgical procurement has been completed and the islet isolation process is performed several hours later at the transplant center. Consequently, millions of dollars in grants intended to fund islet transplantation research are now needed to cover the costs that OPOs are required to allocate to pancreata that are not transplanted.

The problem is exacerbated by ambiguous language in the preamble to the CMS regulations and certain instructions issued by the Medicare intermediary to OPOs, which are being interpreted by some OPOs to preclude them from charging a lower rate for pancreata that yield islets that do not meet applicable release criteria and that are not ultimately transplanted— pancreata that account for approximately 50% of those procured for islet transplants.

We believe that these problems can be resolved through relatively simple adjustments to CMS-mandated cost accounting practices and related policies to: (a) require that the "Intent to Transplant" be determined after the islet isolation has been completed and full cellular product release testing is performed and (b) mandate that OPOs adopt different cost allocation rules for pancreata retrieved for islet transplants than for pancreata retrieved for whole organ transplantation (i.e., treat organs procured for islet transplantation as "a metabolically active tissue" rather than solid organs).

Because these CMS policies implicate the missions of a number of agencies within the Department, we request a meeting to discuss these issues at further length, and further request the participation of representatives of the NIH, HRSA, and other agencies within the Department with an interest in furthering islet transplantation research. Ms. Katrina Crist, ASTS Executive Director, will be contacting your office to arrange a meeting date in the near future. Thank you, in advance, for your consideration of these important issues.

Sincerely yours,

Goran B. Klintmalm, MD, PhD, FACS
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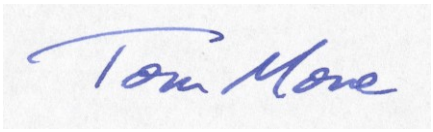

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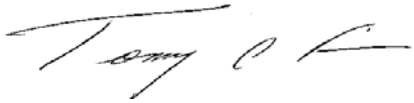

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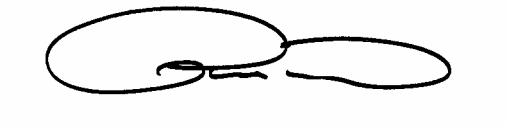

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