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Celebrating 25 Years of Promoting Excellence in the Field of Transplantation

Testimony Before The

United States House of Representatives

**Information Policy, Census and National Archives Subcommittee
Oversight and Government Reform Committee**

**"Organ Donation: Utilizing Public Policy and Technology to
Strengthen Organ Donor Programs"**

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Good morning Chairman Clay, Ranking Member Turner and members of the Information, Policy, Census and National Archives Subcommittee of the Oversight and Government Reform Committee. On behalf of the American Society of Transplantation, representing the majority of our nation's professionals engaged in solid organ transplantation, we applaud your leadership for convening this forum today to focus on organ donation and our nation's ability to deliver the "The-Gift-Life" to the thousands of patients currently awaiting a life saving donor organ. My name is Dr. Jeff Crippin and I am the Immediate Past President of the American Society of Transplantation and the Medical Director of the Liver Transplant Program at Barnes Jewish Hospital in St. Louis, Missouri.

The American Society of Transplantation (AST) states in our mission statement, that we are "...an international organization of transplant professionals dedicated to advancing the field of transplantation through the promotion of research, education, advocacy, and organ donation to improve patient care." Our interests and mission are very consistent with the title of today's hearing, "Utilizing public policy and technology to strengthen organ donor programs", and we are pleased that this Subcommittee is meeting here today to discuss and examine how we can strengthen the nation's solid organ transplant system.

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**AMERICAN TRANSPLANT
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In addition to this hearing, the AST would like to applaud Chairman Clay (D-MO), Congressman Dave Camp (R-MI), Congressman Jim Costa (D-CA), and Congresswoman Ileana Ros-Lehtinen (R-FL) for reviving the Congressional Organ and Tissue Caucus. Your leadership in educating and raising the awareness and visibility of transplantation and the "gift-of-life" is greatly appreciated by the entire transplant community. Thank you.

The Bottom Line – Supply Does Not Meet Demand

As others have already outlined before this Subcommittee, the challenge in our field is the fact that over 97,000 individuals are currently awaiting a life-saving donor organ. Approximately 73,000 patients are awaiting a kidney, over 16,000 are awaiting a liver, 2,600 for a heart, 2,300 for a lung, and 1,600 for a pancreas. Between January and June of this year, we performed approximately 14,000 transplants with 11,083 deceased donor organs and 3,200 living donor organs.

Clearly the math is not difficult to understand why meeting patient's needs are so difficult in this environment of scarce resources. It also speaks to the fact that protecting a patient's life saving donor organ is critical. Optimal care for transplant recipients is crucial to their long-term survival. The medical problems facing the transplant patient are complex and require the attention of physicians trained in transplant medicine. However, the insurance industry often dictates the care of transplant recipients and may prevent patients from returning to a transplant center for medical management. This practice can lead to less than optimal care and, unfortunately, decreased survival rates. Furthermore, transplant centers are held accountable for the survival of their patients, even when they are prevented from delivering the appropriate care. Thus, the AST supports initiatives that guarantee long-term patient follow-up at the patients transplant center or an appropriate center within the patient's geographic region.

In an effort to protect the scarce resource of a donor organ, AST supports the following initiatives:

- Extension of coverage of immunosuppressive medications for the lifetime of the transplanted organ;
- Patient access to their transplant center;
- Access to insurance coverage, especially for pediatric patients; and
- Development of programs for patient and professionals education regarding early treatment of diseases that frequently leads to the need for organ transplants.

Education and Awareness – Patients & Physicians

The AST knows the education and awareness of patients and physicians alike is crucial to the delivery of effective health care. The Society has developed several educational programs to provide updated information on issues regarding organ failure and its complications, the transplant evaluation, and the transplant procedure itself. The organization has crafted a program devoted to the care and maintenance of a transplant after it has occurred. Through these efforts, the AST strives to minimize and eliminate any questions or confusion that may arise as a patient is considering this life

saving surgery before and after transplant. The Society is also actively involved in the education of physicians.

Specifically, we have a number of efforts directed at physicians not actively involved in transplant programs, but involved in the care of patients with organ failure, so a timely referral can be made to the local transplant center. The goal of these programs is to insure that all Americans have equal access to solid organ transplantation. The issue, Chairman Clay and members of the Committee are the unfortunate ignorance of those not familiar, both physicians and patients, with the criteria for transplant candidacy and outcomes. Our programs seek to address these gaps in education. That said, more needs to be done to educate the community.

In my own institution in Missouri, Dr. Amy Waterman, a social psychologist and Assistant Professor of Medicine in the Division of General Medical Sciences at Washington University, is conducting groundbreaking work examining increased patient awareness regarding kidney transplantation. Waterman is currently developing living kidney donation materials focusing on racial differences in attitudes about diabetes and organ donation. Part of her work is funded by the Health Resources & Services Administration (HRSA) through a grant looking at educating patients at kidney dialysis centers about the availability of kidney transplantation. The data obtained by Dr. Waterman and her colleagues will hopefully lay the groundwork for similar programs across America, as we continue to fight the battle against the misinformation and lack of information regarding this life saving therapy.

Outreach to Underserved Patient Populations

In an effort to reach patients in areas that remain underserved and not necessarily knowledgeable about transplantation, I have spent the last four years conducting patient outreach clinics in rural areas of my own home State of Missouri. Although my medical institution is based in St. Louis, many rural citizens across the State of Missouri are not able to travel to the city for education, evaluation, possible diagnosis, and treatment. To combat this situation, I and my colleagues have established clinics in underserved areas such as Cape Girardeau, MO. Cape Girardeau is a town approximately 120 miles southeast of St. Louis with a population of 70,000.

For various reasons, many of the town's citizens do not like to leave or travel to large urban settings and will refuse a referral to St. Louis or other large cities, in spite of a defined need. My presence and that of my colleagues has allowed these patients and their physicians to see the need for solid organ transplantation and simplified their need.

Addressing Disparities in Solid Organ Transplantation

In 2002, end stage renal diseases (ESRD) Medicare (CMS) program costs \$17 billion or 6.7 percent of the overall budget. In the United States, ethnic minorities suffer disproportionately from kidney diseases. African Americans comprise 35 percent of the Medicare dialysis population. Compared to Caucasians, the incidence of ESRD in African Americans is 4-fold higher than that of Caucasian counterparts. This is also true for Native Americans among Zuni Indians in the American Southwest in whom renal

disease in 18-fold more prevalent than for Caucasians. Hispanic Americans have 2-fold the rate of ESRD of non-Hispanic Caucasians.

The excess burden of kidney disease in minority populations reflects, in part, the higher rate of known medical and environmental risk factors for ESRD and for other end-organ failure, including genetic predisposition, diet, lifestyle, Type II diabetes mellitus and hypertension and delays in receiving appropriate treatment. In the Native American dialysis population, 73 percent are diabetic and 83 percent are hypertensive. In African Americans, hypertension is prevalent and less well controlled by conventional medical therapies.

The Diversity and Minority Affairs Committee of the AST convened a symposium to examine organ transplantation in underserved and minority populations. The goals of the meeting included “benchmarking” of solid organ transplantation among minority populations, review of the epidemiology of the end-organ damage, exploration of barriers to transplantation services and development of approaches to eliminate disparities.

Participants in the symposium noted that minority populations were more likely to be adversely affected by limited preventive medical care, lack of counseling regarding transplant options, and delays in transplant referrals for organ transplantation. These features largely reflect economic disadvantage as well as the reduced presence of minority professionals with training in transplant-related specialties.

Participants in the conference noted that recent changes in organ allocation policies had improved access to minority individuals once listed for renal transplantation. Similar advances will be needed for other organs to address inequities in pre-transplant care and under-representation of minorities among transplant professionals. The biologic basis of differences in transplant outcomes for minority recipients has not been adequately studied. Research funds must be targeted to address biologic mechanisms underlying disparate transplant outcomes including the impacts of environment, education, poverty and lifestyle choices.

Removing Financial Disincentives – Family and Medical Leave Policies

In 1999 the AST and other transplant organizations worked closely with Congress to pass and enact legislation providing up to six weeks of paid leave for federal employees seeking to donate a life saving donor organ. Congressman Elijah Cummings of Maryland spearheaded this initiative in the House of Representatives.

In addition to federal leave laws, the AST initiated its own private campaign entitled the, “AST Employee Leave and Donation Program.” The purpose of this campaign is for our transplant physician members to reach out to corporate American and encourage them to amend their employee leave policies to allow adequate time for employees to serve as a living donor. This effort has resulted in many company’s changing their rules and removing a financial disincentive to donation.

Insurance Coverage, Immunosuppressive Medications – Preserving the Life of the Life Saving Organ

One of the greatest barriers at every stage of the organ transplantation process to many individuals is the lack of insurance coverage. This barrier exists from the time a prospective recipient is eligible for listing on the transplant wait list and persist after the transplant itself. Once a recipient receives an organ transplant, the AST and its membership supports measures to ensure that the care for patients are optimized and that the transplanted organ will last as long as possible. To this end, a most important objective is the support of legislation providing coverage for immunosuppressive medication for the lifetime of the transplanted organ. To clarify, patients must take immunosuppressive anti-rejection medications for the life of their transplanted organ.

For many years, the federal government would pay for a transplant operation but only cover 36 months of transplant immunosuppressive drug medications. This was obviously a flawed policy that resulted in patients losing their transplanted organ, returning to dialysis in the case of kidney, or losing their life. From a pure cost perspective it also proves to be more expensive to return individuals to dialysis and/or re-transplant.

As you know Mr. Chairman, last month Congressman Dave Camp (R-MI) introduced a bipartisan measure, H.R. 3282 to cover gaps in Medicare program coverage for immunosuppressive drugs. The legislation, the "Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act of 2007", supported by you and other members of the Subcommittee, would be a solid step forward toward ensuring that transplant patients remain healthy.

The AST supports initiatives that ensure the coverage of immunosuppressive medications for the lifetime of a transplanted organ, regardless of age and ability to pay. Ultimately, this will lead to improved transplant success rates and the greater ability of transplanted recipients to return to a normal life.

Mr. Chairman, Ranking Member, and Members of the Subcommittee, the AST thanks you for the opportunity to participate in today's forum. We applaud and commend your leadership and efforts on this important issue.

The "gift-of-life" though often surrounded by tragic circumstances, can prolong the lives of affected Americans, allowing them to maintain their roles as active and productive citizens of our great nation.