



December 14, 2010

The Honorable Howard Koh, MD, MPH
Assistant Secretary for Health
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: Meeting with You to Discuss Organ Transplantation Oversight Policy Development

Dear Secretary Koh,

The American Society of Transplantation (AST) and the American Society of Transplant Surgeons (ASTS) represent the majority of professionals caring for people awaiting or receiving life saving organ transplants. Our members encompass the entire transplant arena and are keenly aware of the risks and benefits associated with transplanting human organs. Our organizations are very concerned regarding mixed policy messages from the agencies within HHS as it relates to the oversight of solid organ transplantation.

In the absence of a coordinated and reconciled process, the effect on the transplant community has been and will continue to be disruptive and potentially harmful to our patients. While these differences may be understandable, the transplant community needs HHS policy and goals to be clear, consistent and transparent. Specifically, recent efforts to align the responsibilities of oversight of the HRSA/OPTN transplant system with CDC interests of public safety have led to disparate opinions between these agencies regarding biovigilance efforts for the nation's organ supply. The CDC has expressed the opinion that Nucleic Acid Testing (NAT) for transmissible blood borne pathogens should be mandatory for all organ donors. CMS has recently mentioned to the OPO community that donor NAT may become mandatory. While routine application of this process sounds logical, experts from the AST and ASTS in conjunction with others within the field published a consensus paper on the subject earlier this year. It was the conclusion from the community that the routine application of NAT to the standard organ donor would likely result in more deaths from a reduction in organ donors from false positive tests than prevention of transmitted diseases (Am J Transplant 2010; 10(4):889-99). Hence, OPTN policy has not been changed to endorse the NAT recommendation. While the impetus for a reconciliation process at this time is the biovigilance issue, there are other instances where HHS agencies (CMS and HRSA/OPTN, in particular) have differing perspectives regarding transplant policy, oversight and enforcement. The possibility that CMS may move to alter credentialing requirements for the country's organ procurement organizations is another example of an issue that may require internal reconciliation.

Therefore, the AST and ASTS respectively request:

- An opportunity to meet with you and your staff to further discuss the transplant community's concerns, and;
- The development of a clear and transparent reconciliation process within HHS to address inter-agency differences on transplant policy issue oversight.

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Transplantation experts should be involved to provide expertise and insights into the consequences, intended and unintended, of well-intentioned regulations on transplant patients, transplant centers, and OPOs. The stakes for those awaiting life saving donor organs is high and, on behalf of our patients, the AST and ASTS remain committed to continuing to work closely with HHS to optimize the process.

We are very appreciative of your attention and look forward to meeting with you in the very near future.

Sincerely,



Maryl Johnson, MD
President
American Society of Transplantation



Michael Abecassis, MD, MBA
President
American Society of Transplant Surgeons

cc: The Honorable Thomas Frieden, MD, MHP,
Director
Centers for Disease Control and Prevention, Department of Health and Human Services

The Honorable Donald Berwick, MD, MPP
Administrator
Centers for Medicare and Medicaid Services, Department of Health and Human Services

The Honorable Mary Wakefield, RN, PhD
Administrator
Health Resources and Services Administration, Department of Health and Human Services

The Honorable Margaret Hamburg, MD
Commissioner
Food and Drug Administration, Department of Health and Human Services