June 6, 2011

Dr. Jerry Holmberg
Senior Advisor for Blood Safety
Office of the Assistant Secretary for Health - Office of the Secretary
U.S. Department of Health and Human Services
1101 Wootton Parkway
Tower Building, Suite 250
Rockville, MD 20852

Re: RFI Regarding Interest in Biovigilance and Public-Private Partnership

Dear Dr. Holmberg,

On behalf of the American Society of Transplantation (AST) and the American Society of Transplant Surgeons (ASTS), representing the majority of physicians, surgeons, and other professionals engaged in the field of organ transplantation, we thank you for the opportunity to comment on the U.S. Department of Health and Human Services' (HHS) request for information (RFI) to identify and obtain relevant information from public or private entities with an interest in biovigilance.

As you know from our ongoing correspondence, task force and advisory body participation, as well as meetings with you and HHS Assistant Secretary for Health, Dr. Howard Koh, our organizations represent significant healthcare community stakeholders concerned with all aspects of transplantation. AST and ASTS share the Department's commitment to the establishment of a comprehensive national biovigilance program. Both organizations have a long and rich history of collaboration and partnership with many local and federal health care agencies with respect to policy development. We strongly support the concept of utilizing public/private partnerships (PPPs) to facilitate the identification of risks and strategies in the biovigilance arena, and we offer our resources, expertise and professionals to assist the Agency as it moves forward in this endeavor.

However, we urge the Department to reconsider whether it is appropriate to establish a single public private partnership with consolidated oversight of the safety of both blood/tissues and organs. As set forth in the Joint ASTS/AST Task Force on Biovigilance Consensus Statement, **"**A Single Biovigilance System for blood, tissue and organs: Square pegs in round holes?" ("Joint Task Force Consensus Statement")(attached), the public policy considerations involved in biovigilance efforts for organs differ in a number of critical ways from those impacting blood/ tissues.

The "gap analysis" set forth in Public Health Service Biovigilance Task Group's October 2009 report, "Biovigilance in the United States: Efforts to Bridge a Critical Gap in Patient Safety and Donor Health" identified two "gaps" in the nation's biovigilance efforts as those efforts

specifically apply to organs: *Gap 15: Lack of nationwide common organ/tissue donor network system for real-time reporting, data collection, communication, and analysis of donor transmitted diseases in organ and tissue transplant recipients, including a common donor identifier necessary for linkage back to implicated donor of both organs and tissues* and *Gap 16: No Requirement to retain donor and recipient samples*. The latter currently is being addressed through the AOPO Standards and Accreditation Manual (Safety Standard 2.0) and through a policy proposal change within UNOS/OPTN, which would establish an effective mechanism for assuring that organ samples are stored for 10 years following donation, and we believe that this policy should be implemented as soon as feasible, consistent with the Public Health Service's recommendations..

We also agree with that portion of the October 2009 Public Health Service report (Gap 15) that identifies the need to establish a common donor identifier necessary for linkage back to implicated donors or both organs and tissues. We believe ISBT 128 or a similar system establishing a common labeling code would permit rapid recipient identification of tissue products and organs from a common donor. The transplant community stands willing to assist in the identification and implementation of the best system to accomplish this critical goal expeditiously.

However, as set forth in the Joint Task Force Consensus Statement, the issues surrounding the safety of the Nation's organ supply are complex, involving multiple factors in addition to the prevention of disease transmission. We remain unconvinced that the multiplicity of unique factors involved in assuring organ safety and availability are best addressed through a uniform public-private partnership that also must be organized and operated to address the biovigilance issues related to blood and tissue safety.

In the National Organ Transplant Act, Congress specifically vested authority to oversee organ donation, allocation and transplantation in the Organ Procurement and Transplantation Network (OPTN), a private nonprofit entity whose board of directors includes individuals with broad expertise in various aspects of organ donation and transplantation. More recently, the Centers for Medicare and Medicaid Services has supplemented OPTN standards with Medicare certification standards which also address organ safety and other aspects of quality assurance in transplantation. In contrast, by law the Food and Drug Administration (FDA, a federal agency with significantly different expertise and a much more narrow scientifically focused mission, oversees blood and tissue (and cell) retrieval, processing and distribution, irrespective of whether the deceased donor also gave organs. Thus, Congress and HHS both historically have envisioned very different oversight mechanisms for organ donation/ transplantation and for blood and tissue safety.

Perhaps more importantly, however, due to the relative scarcity of organs available for transplantation, the time limitations required to complete safety assessments, and a myriad of other factors described in detail in the Joint Task Force Consensus Statement, biovigilance processes for organs necessarily must differ from those applicable to the blood and tissue supply. As set forth in the Joint Task Force Consensus Statement, the only strategy that would totally eliminate the risk of transmitted disease would be to stop transplanting organs. The balance between biovigilance and organ availability is a particularly unique and delicate one: The lives of organ recipients hang in the balance between assuring complete organ safety and unknowingly assuming the risk of disease transmission. The same risk/benefit equation simply does not apply in the case of blood and tissues. The type of public-private partnership necessary to address the safety of the Nation's blood and tissue supply most effectively and expeditiously necessarily will not represent the nuanced breadth of interests and expertise necessary to assure that the proper balance is struck between organ safety and organ availability. (See "Nucleic Acid Testing (NAT)

of Organ Donors: 'Best' Test the Right Test? A Consensus Conference Report," American Journal of Transplantation (attached)).

For these reasons, we urge HHS to:

- Recognize that one of the biovigilance "gaps" identified with respect to organ safety already is being addressed by the OPTN and AOPO through the establishment of standards requiring the storage of organ samples for 10 years post-donation;

- Work with ASTS and AST as well as other stakeholders to establish a common labeling system for organs, blood and tissue to facilitate the communication of information regarding disease transmission;

- Establish parallel biovigilance public/private partnerships, with one process focused on disease transmission in the blood and tissue supply and the other focused on balancing biovigilance concerns against other critical factors that must be taken into account in the context of organ transplantation; and

- Ensure the active involvement of all divisions of the Department of Health and Human Services (including, for example, HRSA, CMS, OPTN, and the FDA) and the affected transplant community (ASTS, AST, AOPO, and transplant centers) in the public-private partnership focused on biovigilance as it relates to transplantation.

The AST and ASTS applaud HHS for its leadership and commitment to protecting the nation's blood, tissue and organ supply. We look forward to continuing to serve and work closely with the Department on biovigilance and all issues impacting public safety and the field of organ transplantation. If you have any questions or concerns, please do not hesitate to contact us directly.

Sincerely,

Robert S. Gaston, MD
President, AST

Mitchell L. Henry, MD
President, ASTS

cc: Howard Koh, MD, MPH

Attachments

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