

## AST Position on Conflict of Interest in Medical Research, Education and Practice With Specific Reference to the Institute of Medicine Full Recommendations of 4-28-09

The American Society of Transplantation (AST) is an organization representing more than 4,000 transplant professionals dedicated to advancing the field of transplantation and improving patient care by promoting research, education, advocacy, organ donation, and service to the community. Its primary mission ultimately relates to fostering improved care for transplant recipients, donors, and their respective families. The AST recognizes that there are exceptional circumstances inherent in the practice of organ transplantation, and as such, acknowledges the intrinsic responsibility associated with the stewardship of a precious resource for the care of deserving patients. Thus, issues related to the proper dispatch of the AST's duties, both with regard to their substance and appearance, are critical to the AST's sustained effectiveness.

Modern medical practices, such as those vital to the conduct of organ transplantation, have evolved through close collaborations with many groups sharing the common desire to improve patient outcomes. These include (501) (c) (3) registered charitable organizations and foundations such as the AST, federal agencies, and commercial entities. The AST has also fostered appropriate relationships with groups from all of these categories in pursuit of its primary mission. Specific attention has been focused on the nature of relationships between individuals and organizations serving medical research, education and practice, and organizations gaining profit from medical activities, particularly pharmaceutical, medical device, and biotechnology companies. This attention has been appropriately drawn by circumstances in which there has been real or perceived conflict of interest between medical practitioners and for-profit companies. In April 2009, the Institute of Medicine (IOM) published specific recommendations to aid in maintaining appropriate relationships between organizations with interests in medical care. In general, the report recognizes that data is limited regarding the extent to which conflicts result in biased decision-making, or direct harm to patients; however, the IOM's action at this time has been driven by the growing sense that conflicts can and do erode the public's trust in physicians and the research enterprise. Given the fundamental requirement for trust in an altruistic exchange such as organ transplantation, the AST has taken specific note of this report.

In general, the AST has long recognized that there is a clear potential for commercial entities, particularly those involved in medical drug and device development, to exert influence on its mission. Accordingly, the AST has developed specific guidelines to eliminate the potential for conflicts of interest. Importantly, the AST has also recognized the long-standing synergy in its appropriate relationships with for-profit entities. The AST supports processes that preserve appropriate relationships and eliminate inappropriate relationships.

With specific reference to the IOM guidelines, the AST has developed, adopted, implemented and made public conflict-of-interest policies consistent with the recommendations in the IOM report. It has long had rules established for full disclosure of financial relationships between its officers and pharmaceutical, medical device, and biotechnology companies. It has established standard content, formats, and procedures for the disclosure of financial relationships with industry. Methods are in place for disclosure of potential conflicts related to all disbursements of research grants and other AST funding. AST's board members are already bound to the code of ethics outlined in the recommendations. The AST agrees that companies should not involve physicians or patients in marketing projects that are presented as clinical research and supports industry regulations to avoid gifts or inappropriate compensation of AST members.

The IOM report recommends establishing a new system of funding accredited continuing medical education (CME). Legitimate CME is critical to the sustenance of a medical career, and the AST is committed to serving the transplant community in providing high quality, unbiased CME opportunities. At present, the Accreditation Council for CME (ACCME) creates the rules and foundation for CME. The AST has been proactive in abiding by these rules and all CME activities are conducted by organizations meeting ACCME certification. The AST has made great efforts to keep CME separate from any external influences.



Funding by for-profit entities has supported a portfolio of CME programs, grants and awards, and these resources have been appropriately leveraged in fiscally limited times. Funding has been carried out via a pooled resource defined by the AST membership, and rigorous peer review modeled after the National Institutes of Health peer review system. The AST will remain diligent in implementing policies to comply with regulations as they are implemented, either through the ACCME or a new oversight organization. In the absence of alternative sources of funding, the AST will continue to support appropriately vetted funding for legitimate, unbiased CME activities and grants consistent with the contemporaneous applicable regulations.

The AST continues to provide valuable practice guidelines and general informational publications for members and the general public. The AST strongly agrees that these materials should be developed by panels that are free of conflict. The society will not accept funding for development of these practice guidelines. The AST, in collaboration with the ASTS, publishes the premier transplant journal, the American Journal of Transplantation. All authors are required to declare conflicts and the Journal has a published policy handling conflicts of interest for all authors and Board members.

The AST also has a policy regarding conflict of interest disclosure for all Board members. In response to the IOM recommendations, the AST has also established a standing committee on Society conflicts of interest.

In summary, the AST has proactively established guidelines similar in content and identical in intent to the IOM recommendations on managing conflicts of interest. The Society will continue to provide unbiased informational and support services to the transplant community and remain diligent in maintaining appropriate relationships with all relevant interested transplant-related parties.

Approved by the AST Board of Directors, May 29, 2009
Revised and approved by the AST Board of Directors, September 6, 2011
Revised and approved by the AST Board of Directors, March 3, 2020

## **American Society of Transplantation (AST)**

1120 Route 73, Suite 200 Mount Laurel, NJ 08054 Phone: (856) 439-9986 Fax: (856) 439-9982

Email: <a href="mailto:info@myAST.org">info@myAST.org</a>
Website: <a href="mailto:www.myAST.org">www.myAST.org</a>

## Contact:

Shandie Covington, Executive Director, <a href="mailto:scovington@myast.org">scovington@myast.org</a>; 856-316-0924

Bill Applegate, Director of Government Relations, <a href="mailto:bill.applegate@bclplaw.com">bill.applegate@bclplaw.com</a>; 202-258-4989