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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Committee on Blood and Tissue Safety and Availability

**AGENCY:** Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

**ACTION:** Notice.

**SUMMARY:** As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services is hereby giving notice that the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) will hold a meeting. The meeting will be open to the public.

**DATES:** The meeting will take place Monday November 28, 2016, from 9:30 a.m. – 4:00 p.m. and Tuesday November 29, 2016, from 8:30 a.m. – 4:00 p.m.

**ADDRESSES:** Veterans' Health Administration National Conference Center, 2011 Crystal Drive, 1<sup>st</sup> floor Conference Center, Crystal City, VA 22202.

**FOR FURTHER INFORMATION CONTACT:** Mr. James Berger, Designated Federal Officer for the ACBTSA, Senior Advisor for Blood and Tissue Policy, Office of the Assistant Secretary for Health, Department of Health and Human Services, Mary E. Switzer Building, 330 C Street, SW, Suite L100, Washington, DC 20024. Phone: (202)-795-7697; Fax: (202)-691-2102; E-mail: [ACBTSA@hhs.gov](mailto:ACBTSA@hhs.gov)

**SUPPLEMENTARY INFORMATION:** The ACBTSA provides advice to the Secretary through the Assistant Secretary for Health. The Committee advises on a range of policy issues to include: (1) identification of public health issues through surveillance of blood and tissue safety issues with national biovigilance data tools; (2) identification of public health issues that affect availability of blood, blood products, and tissues; (3) broad public health, ethical, and legal issues related to the safety of blood, blood products, and tissues; (4) the impact of various economic factors (e.g., product cost and supply) on safety and availability of blood, blood products, and tissues; (5) risk communications related to blood transfusion and tissue transplantation; and (6) identification of infectious disease transmission issues for blood, organs, blood stem cells and tissues. The Committee has met regularly since its establishment in 1997.

In December 2013, the Committee made recommendations regarding the blood system. At that time, the Committee expressed concern about the ongoing reductions in blood use, the number of large scale consolidations occurring, the cost recovery issues for blood centers, and the potential effects on safety and innovation due to instability. In November 2015, the Committee made recommendations again, reaffirming the December 2013 recommendations, highlighting the worsening conditions, and suggesting potential initiatives to address the issues in the blood system. Past recommendations made by the ACBTSA may be viewed at

<http://www.hhs.gov/ohaidp/initiatives/blood-tissue-safety/advisory-committee/index.html>.

The Committee will meet on November 28-29, 2016 to hear the findings from the HHS sponsored RAND study, “Toward a Sustainable Blood Supply in the United States: An Analysis of the Current System and Alternatives for the Future.” The ACBTSA Subcommittee on Blood System Sustainability will present their response to the study, and the full Committee will

discuss and develop appropriate recommendations for HHS consideration. Additional topics that are pertinent to the mission of the Committee may be added to the agenda.

The public will have an opportunity to present their views to the Committee during public comment sessions scheduled for both days of the meeting. Comments will be limited to five minutes per speaker and must be pertinent to the discussion. Pre-registration is required for participation in the public comment session. Any member of the public who would like to participate in this session is required to submit their name, email, and comment summary prior to close of business on November 17, 2016. If it is not possible to provide 30 copies of the material to be distributed at the meeting, then individuals are requested to provide a minimum of one (1) copy of the document(s) to be distributed prior to the close of business on November 17, 2016. It is also requested that any member of the public who wishes to provide comments to the Committee utilizing electronic data projection submit the necessary material to the Designated Federal Officer prior to the close of business on November 17, 2016.

**DATED: \_\_October 18, 2016**

James J. Berger

Senior Advisor for Blood and Tissue Policy

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