

**U.S. Department Of Health And Human Services
Advisory Committee For Blood Safety And Availability
39th Meeting Minutes**

November 4 and 5, 2010

The Universities at Shady Grove
9630 Gudelsky Drive
Rockville, Maryland

Thursday, November 4, 2010

Opening Remarks: Dr. Jerry Holmberg, Executive Secretary for the Advisory Committee for Blood Safety and Availability (ACBSA) and Designated Federal Official, welcomed committee members to the 39th meeting of the ACBSA.

Announcement of new Members: Dr. Holmberg introduced the new Chair Dr. Michael G. Ison, Assistant Professor, Division of Infectious Diseases and Organ Transplantation, Feinberg School of Medicine, Northwestern University, was introduced to the committee. Also introduced were two new patient advocates on the committee, Edward Burke and Alissia Cofer, and the new AABB replacement, Dr. Jay Menitove.

With the permission of the Committee Management Office, Dr. Quinlan, Mr. Vogel, and Dr. Lopez were invited as guests to the meeting. Dr. Laura St. Martin, Office of Office of Cellular, Tissue and Gene Therapies (OCTGT), Food and Drug Administration (FDA) was asked to be a guest as well.

After welcoming members, Dr. Ison commented on the charter expansion and noting the primary objective is blood but the Committee must realize the same issues that affect blood, affect transplanted organs and tissues. His goal as chair is to seek input from all members and encouraged them to approach him with issues they feel should be brought forward.

Remembrance of Dr. Paul McCurdy

Dr. Holmberg recognized the life and contributions of Dr. Paul McCurdy. Dr. McCurdy passed away on September 7, 2010. Dr. McCurdy was a former board member and respected leader in the blood bank community. He asked for a moment of silence in remembrance of Dr. Paul McCurdy.

Conflict of interest statement was read by Dr. Holmberg.

Swearing in of new members was performed by Ms. Renee Wilson

Roll Call: Representative voting members Dr. Corash and Dr. Axelrod could not be in attendance; however a quorum was present. Dr. Holmberg clarified that each public voting member is considered to be a special government employee (SGE) and required to fill out financial disclosures. Dr. Yomtovian is a regular government employee (RGE), and is considered part of the public voting section.

Charge to the Committee on Strategic Priority of HHS and Affordable Care Act

Dr. Jerry A. Holmberg, Senior Advisor for Blood Policy addressed the committee on behalf of Dr. Koh. The presentation addressed transfusion and transplant safety and current priorities pertaining to alignment with the Secretary's Strategic Initiative and key interagency collaborations. Some initiatives set forth by the Secretary include: transform health care, implementation of the Recovery Act, promote early childhood health and development, weight, prevent and reduce tobacco use, protect Americans in public health emergencies, accelerate discoveries, improve patient care, implement a food safety program, and ensure program integrity and stewardship.

Update on Research Agenda

Dr. Simone Glynn, Branch Chief Transfusion Medicine and Cellular Therapeutics Branch, Division of Blood Diseases and Resources National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH), discussed the NHLBI's strategic research agenda in medicine, concentrating on transfusion. The NHLBI continuously monitors and identifies scientific priorities as well as identification of gaps in research support and funding mechanisms. Although there has been a drastic decrease in transfusion risks such as HIV and HCV, emerging infectious disease (EID) threats must be considered.

Dr. Glynn expressed that NHLBI recognizes the need for further research and support for various areas including:

1. To further define immune consequences of transfusion, as well as to better define the biology and the clinical indications for particular red cell transfusion.
2. Clinical practices, utilization patterns and determinants currently in practice. There should be an effort to try to evaluate best clinical practices. Some areas of notice are platelet transfusion strategies, red blood cell transfusion trigger, evaluation of blood products ratio to trauma patients, and pathogen activation of platelet products.
3. Support for pilot clinical studies, which are key before embarking on a large clinical trials.
4. Lack of an external review panel with expertise in transfusion medicine and lack of grants as impediments.

Dr. Glynn discussed the MINT Trial is a face-to-face clinical trial with two arms for patients with acute coronary syndrome. One arm is getting transfused with red cells when the hemoglobin is 10 or less. The other arm is being transfused when the patients have symptoms or their hemoglobin is 8 or less. It is a focus for cardiac patients.

The Hemostasis Clinical Trials Network is a national network established in 2002 and renewed in 2007. It has 17 clinical centers and structured around one data coordinating center. The goal is to conduct clinical trials evaluating critical issues in transfusion or hemostasis. The Hemostasis Clinical Trials Network establishes priorities while identifying areas of investigation and gaps in research support.

NHLBI encourages investigators to look at small business research and small business transfer grants.

One of the latest projects was initiated in response to the critical need for the development of a U.S. Transfusion Transmitted Marker Hemovigilance Program to better understand the current risk factors and their relative prevalence among non-deferred donors. There are three participating organizations which represent about 60% of all blood donors and donations in the U.S.; that is American Red Cross (ARC), Blood Systems Incorporated (BSI), and the New York Blood Center (NYBC). One area is to investigate the incidence and prevalence of major infectious agents in the blood supply, and the other is a case control study which will be done to evaluate the relative proportion of behavioral risk factors associated with prevalent and incident viral infections in donors. One study launched is the REDS-II XMRV study.

Another large program is the properties of transfused red cells as a function of storage research program. It has three components. Finally, the Red Cell Storage Duration Study which is called RECESS; it is a phase III randomized clinical trial. The primary end point is a change in clinical outcomes assessed using the Multiple Organ Dysfunction Score.

Recipient Epidemiology and Donor Evaluation Study (REDS) III as the name implies focuses on both recipient and donor. REDS III will be launched in 2011. REDS-III will be multi-center program, which will last seven years instead of five. It will have an international and a domestic component, but it will also be charged with conducting an epidemiology survey and lab studies. ACBSA should try to encourage clinical trials to define optimal clinical use and develop clinical guidelines based on scientific evidence, giving additional consideration to how to best support clinical trials in transfusion medicine.

Dr. Klein announced when XMRV arrived and got national and international attention, NHLBI stepped in to fund studies, to investigate assays, and to get a scientific handle on what was happening. Dr. Glynn was able to get a few funds for the XMRV panel study, but this was limited due to tight funds.

It was recognized by the Committee that there is not a REDS equivalent for organ and tissue; the infrastructure isn't there for other issues. Issues of developing a research agenda for human tissues and looking for ways to collaborate with, FDA, Health Resources and Services Administration (HRSA), Centers for Disease Control and Prevention (CDC), and the Agency on Health Research and Quality (AHRQ) related to organ and tissue donors and deceased donors were discussed. At this point, there is little known about risk markers in the organ and tissue community (including patient and donor). It was also recognized that there is no national biovigilance program which would be instrumental in developing tissue/organ research although work is being done by federal agencies, the transplant community, and the organ donation community on trying to develop a national biovigilance program. As a point of clarification, the FDA is charged with oversight of tissue safety while the HRSA is the agency in the HHS that has oversight for the Organ Procurement Transplant Network.

It was also mentioned that there are funding opportunities for small business research in pathogen reduction. While evaluating programs that are being supported, NHLBI looks at what

all agencies do. The Department of Defense also has invested in pathogen reduction research. Dr. Glynn would like to see more research in support in the area.

In terms of global health, NHLBI is interested in supporting global health. They recently established a Global Health Office at NHLBI because of the large initiative related to chronic diseases that was launched. The REDS-II Program at NHLBI was the first program to go international.

Dr. Holmberg expressed hope that the ACBSA obtained a sense of appreciation for the responsiveness of NHLBI to many of the Committee's recommendations. An example of research on the issue of XMRV was given as well as radio frequency identification of blood products which was an outgrowth of the SBIR Program supported through NHLBI. The Donor Hemovigilance Program was developed under the small business approach.

Blood, Organ, and Tissue Senior Executive Council (BOTSEC) and ACBSA Charter

Dr. Holmberg shared with the Committee the BOTSEC function within HHS and the coordination that takes place between the agencies and the department. The mission of the BOTSEC is to serve as the department's internal executive leadership coordination mechanism across all the staff and operating divisions involved in blood, organ, and tissue safety and blood product availability. The internal committee is also responsible for looking at providing timely recommendations on emerging issues that are taking place. It also provides decisional elements on proposed policies, public health threats, and issues related to blood, organ, and tissue safety and availability.

The BOTSEC charter was signed by the senior leadership within the department and within the agencies. The staff of the Public Health Service (PHS) operating divisions involved in blood, organ and tissues safety (BOTS) meet monthly by a teleconference call.

The ACBSA is an external committee which is charged to provide advice to the Secretary and the ASH on public health parameters around safety and availability of the blood supply and blood products, to address broad public health and ethical issues relating to transfusion and transplantation safety, and availability and various economic factors that affect product cost and supply.

An annual report of the ACBSA is required to be posted on the FACA website each year in October. In addition, the blood safety website (www.hhs.gov/bloodsafety) has postings of minutes, transcripts and recommendations of each meeting. The ACBSA Charter requires at least one meeting per year. Over the last several years, the ACBSA has met two to three times per year. To increase the transparency, the ACBSA has moved to webcasting. The FACA requires that notice and scope of an advisory meeting be published in the Federal Registry within 15 days of the meeting but does not require the agenda to be posted. Dr. Ison stated there is always an invitation for public individuals and Committee members to present topics for discussion. Dr. Epstein commented that the historic charge of the ACBSA was to risk communication.

Hemovigilance Update

Blood Donor Module and Launch: Dr. Kevin Land, President/CEO and Medical Director, South Texas Blood & Tissue Center, San Antonio, TX, discussed the update on donor hemovigilance within the framework of the U.S. Biovigilance Network. The blood donor part is just one of the components of what is envisioned to be a robust network. He provided background information into the blood donor reporting piece. In development of the donor aspect of hemovigilance, much time was spent in standardization of terminology. One feature of the donor hemovigilance is denominator data as well as the numerator data for donor adverse events. Data can be uploaded manually or through a special upload report that hard-codes the numbers for minimal effort by staff. Dr. Land showed various ways the data could be manipulated.

There are three major pieces of the database: donor data, donation data, and reaction data. He reflected that implementation of privacy measures to protect facility and donor specific information. His blood center does not capture donor demographics, such as name and address, but they do retain donor identification numbers, dates of birth, gender, and some elements maybe considered public health indicators. Future enhancements are expected to address these privacy concerns.

Hemovigilance Update

Blood Recipient Module and Launch

Dr. Matthew Kuehnert, FACP, Director, Office of Blood, Organ, and other Tissue Safety, Division of Healthcare Quality Promotion, CDC, started his presentation by taking a step back to give background information. HHS defined biovigilance as a comprehensive and integrated national patient safety program to collect, analyze, and report on the outcomes of collection and transfusion, transplantation of blood components and derivatives, cells, tissues, and organs. The term “bio” is used to mean a comprehensive interpretation of blood and blood products. Biovigilance is when organs, tissues, and cells are added. His focus was on recipient surveillance and adverse events, including reactions that patients have and errors or near-misses that may occur.

Hospital transfusion services and blood centers have a mandatory requirement to report serious reactions and fatalities. The ACBSA recommended that government and the AABB formed a Task Force on Biovigilance to develop a patient safety program. This task force recommended CDC and AABB to form a partnership to develop a hemovigilance system using the National Healthcare Safety Network (NHSN) of the CDC. The general belief is that the regulatory approach is very important, but there is also a public health approach to adverse event data collection that needs to be considered. As more data are collected, data summits with expert working groups can develop complimentary reports that can be studied in order to continue the cycle and evaluate new interventions.

Dr. Kuehnert explained that CDC developed a cooperative agreement with the United Network for Organ Sharing (UNOS), a project to look at the possibility of a communication network to detect transmissions. He emphasized that a foundation infrastructure is needed in regard to

tissue and organ donation. He expressed that there is a need for overall education to increase recognition and awareness of adverse event reporting in organs and tissues including public health officials. Health departments need staffs that understand investigation, surveillance, and policy. The first step of organ and tissue is the harmonization nomenclature and common definitions.

Dr. Klein asked about the awareness of biovigilance in the medical community and if there is anything published regarding hemovigilance has been published in the medical literature. Dr. Kuehnert expressed that there is a pressing need to write a methods paper and his team is in the process of doing that now.

It was asked of Dr. Kuehnert if plasma-derived products are held to a different standard than the plasma component of transfused blood; and can plasma component be held to a higher standard? Is it potentially treatable to reduce the pathogen risk? Can plasma products be held longer before it is transfused? In response, it was stated the Hemovigilance Model gathers data that will be analyzed for process improvement. The ACBSA recommended a high priority on the development of validated pathogen reduction technology for all components. The FDA did approve a solvent detergent pulled plasma product made by Vitex, which was unfortunately taken off the market due to thrombosis incidents at a single hospital. Further submissions of pathogen reduction methodologies would be entertained.

National Blood Collection and Utilization Survey Report

Dr. Jerry Holmberg, Senior Advisor for Blood Policy, started his presentation by explaining the 2005, 2007 and 2009 National Blood Collection and Utilization Survey (NBCUS). The survey reports include the introduction, methods, findings, biovigilance, and hospital costs of blood products but not plasma fractionation products. Details of the current 2009 survey were presented and compared to previous reporting periods. Blood collection, distribution, and utilization may be in excess of \$10 billion. There were 16,000 severe donor reactions were reported, which maybe underreported. Regarding tissues, 76% of the surveyed institutions reported an inventory of using human tissues for transplantation.

The current survey identified that 19% of the collections represented the 16-25 age group however median age was not determined since it calculation of median age would require frequency of donor by age submitted by each blood center. Benchmarking of blood centers with others using national data is important for process improvement.

Lastly, a comment was made that many hospitals are looking at blood management programs. There is a more global awareness at the practice level to bring down use. Future survey's may reflect attempts to ensure better blood utilization as more hospitals move for patient blood management.

Review of FDA Fatality and Blood Product Deviation Report (BPDR) for Blood and Tissue

Mr. Gilliam Conley, Center for Biologics Review and Evaluation, FDA, discussed the required reporting system. He was asked to do a five-year summary and report on anything that has been

noted, or is a concern to the agency. Facilities are required to report fatalities that are associated to a transfusion. Biological reporting is any event that may affect the safety, purity, or potency. Reports are based on a fiscal year that ends at the end of September as part of the quality management system.

The 44 fatalities for fiscal year 2009 did not include the eight that were found to not be transfusion related. Mr. Conley wanted to draw the committee's attention to the fact that the number of transfusion related acute lung injury (TRALI) events are declining on the first line. Red blood cells components were the most likely implicated in TRALI reports. The general decline is most likely due to using male donors for plasma large donors.

In follow-up, Mr. Conley stated FDA is watching marker rates and doing quality assessments internally, but they need to push the biovigilance aspect.

Secretary's Strategic Initiatives

- **Office of the Assistant Secretary for Health Alignment**
- **Impact of the Affordable Care Act (ACA)**

Dr. Anand Parekh, MPH, Deputy Assistant Secretary for Health, Science, and Medicine, Office of Assistant Secretary for Health (OASH), thanked the Chair and Dr. Holmberg, for his steadfast stewardship. Dr. Parekh listed the Strategic Initiatives: the Affordable Care Act, the stimulus, early childhood health, maintaining healthy weight, reducing tobacco use, accelerating the process of scientific discovery to improve patient care, and implementing a food safety system. There may be opportunities for alignment with other HHS agencies in regards to teen and unintended pregnancies, supporting the national HIV and AIDS strategy, and improving global health. Dr. Parekh gave detail on each initiative and how OASH helps provide leadership across the departments. A point was raised that the committee is focused on blood, organ, and tissues and the opportunity to address transfusion dependent conditions and transplantation issues in the Strategic Initiative.

Dr. Jay Epstein pointed out the recommendations of the ACBSA does not get all of the institutional support in terms of funding and prioritization of blood issues which creates frustration. The second issue he raised dealt with integration of recommendation into overall strategic plans.

Dr. Kuehnert summarized the discussion by expressing keywords that ran through the discussions such as alignment and preparedness.

Lastly, the committee members had a lengthy discussion regarding transplants.

Discussion

It was pointed out that the Committee does a great job in discussing problems and making recommendations, but not so affective at figuring out how to move the system. It was

recognized that funding was an issue in trying to move forward, and wondered how the committee could get additional funding. It was also recognized that reimbursement does not match product costs so that there is nothing left over for safety initiatives. This raised questions and discussion on how to inform the public and influence funding for priority recommendations.

Adjournment

Dr. Ison adjourned the 39th meeting of the ACBSA for the evening.

The ACBSA second day was convened and presided over by Dr. Michael Ison on November 5, 2010.

Opening Remarks: Dr. Ison greeted participants and went through the agenda items for the day. He listed tentative future meeting dates: May 5th and 6th, 2011 and October 5th and 6th, 2011.

Roll call: It is noted a quorum is present.

The conflict of interest statement was read by Dr. Holmberg.

Review of Strategic Priorities in 2005: Dr. Jerry Holmberg covered the strategic priorities from 2005 through 2010. A good portion of the recommendations have been partially implemented in one way or the other, but there is still work that can be done. Many of the recommendations have addition steps that must be completed before actual of the specific recommendation. A summary of the progress will be placed on the portal for the Committee.

Following the June 2010 recommendations of the Committee, the Assistant Secretary for Health (ASH) charged a MSM Working Group (WG) to investigate strategic steps, including scientific research for validation on an alternative MSM policy. The NHLBI has moved forward with the donor risk study. The MSM WG is working on a plan to delivery to the ASH.

Another significant activity from the Committee's recommendation was the ASH formation of the Pathogen Reduction Technology Task Force (PRT TF).

For biovigilance, alignment of funding and transparency, the FDA sponsored a workshop on quantitative blood vigilance in Spring 2010. Biovigilance is needed to bridge a critical gap in patient safety and donor health.

The Joint Commission has looked at blood measure for patient blood management that has the potential to have an impact on transfusion practices

Over the last five years areas identified that need to be considered into the next strategic plan includes: risk communication, error prevention in blood collection centers, blood transfusions, donor recruitment and clinical practice standards for transfusions, strategic research, disaster planning, reimbursements that is sufficient and sustainable, and funding of new technologies include those for pathogen reduction technology. Discussion at that time was also around policy decisions and desire in 2005 to have a formal statement on acceptable risk versus "zero" risk.

There was a request to have more discussion at a later time on the work of the blood and tissue working group within the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE). This was expressed in light of the modeling for blood and tissue requirements for a radiological/nuclear event.

In 2005 when the Committee identified important issues to be addressed in the strategic plan, the scope was blood safety and availability, the Charter now includes transfusion and transplantation safety, it must include tissue and organ safety.

One of the items emphasized from the Secretary's Strategic Plan was primary care prevention and wellness. Prevention of the need for transfusion through patient blood management was discussed as well as patient safety, research, preparedness, and global health. Lastly it was stated that there are two main areas, the product and the patient.

Open Public Comment Period

Dr. Yomtovian spoke on her colleague, Dr. Michael Jacobs. A platelet study that Dr. Jacobs did in collaboration as the Principle Investigator for Verax was presented. Implementation of the CAP and the AABB Standards for early detection has caused the gram-negative contamination rate to go down. There have been 13 study sites involved with units that have been apheresis. They have undergone bacterial testing by the Verax system by Dr. Jacobs' research lab. In conclusion, a large scale, multi-site study with interim numbers being over 18,000 units document that bacterial contamination continues to be a problem with leukoreduced platelets despite the use of early culture at the rate of 1 in 2,000. There are some false-positives and there was one false-negative. The Verax test is approved by FDA.

Most fatalities from platelet contamination are due to coagulase-negative staph. Even though they are not considered pathogenic, they cause more deaths because of the frequency. The second point is regarding the Secretary's Strategic Initiatives; one of the items is to reduce healthcare-associated infection. If there is not awareness of this as a problem, most clinicians would think this was a catheter-infection, particularly coagulase-negative staph, and would never think it is from the platelet.

Committee Discussion

The Committee was asked to include in the strategic priorities related to organs, tissues, and blood. Dr. Holmberg asked the Committee to discuss its priorities. Identified issues include: key interagency collaboration, protection of the health and safety of Americans in public health emergencies, and accelerating the process of scientific discovery to improve patient care. Other priorities discussed were global health programs that emphasize country ownership, strategic integration and coordination, women-centered programming, health systems strengthening and metrics monitoring, and evaluation and research. Tissues and organs are important and priorities need to be established for them. Questions asked of the Committee included:

1. What are the priorities of the country?

2. What can be done to improve transfusion and transplantation safety and availability as part of the transformation of healthcare? They need to look at transfusion practices and even transplantation practices. Additional areas include biovigilance, informed consent, and donor recruitment and retention.
3. Does the committee feel that the highlighted strategic initiatives are really the key strategic initiatives as they apply to blood, organ, and tissue?

It was suggested the Committee look at the 2005 elements of the Strategic Plan and identify the most important action items.

Discussion of biovigilance occurred. Dr. St. Martin expressed concern that organs and tissues are different and that one size fits all. There are specific issues that need to be addressed for tissues that may have limited crossover to blood. Regarding organs it was agreed by the Committee that alignment and coordination with the OPTN is required. It was agreed that there is going to be a lot of confusion regarding organs versus tissues versus cells. One of the structural problems with the whole process is that while there are all sorts of ideas of what it means to transplant something into someone, the regulatory governance is different. Oversight is very different, but in terms of the surveillance and CDC's activities is the same.

Looking at the global picture, there are four topics that the committee could start on. Biovigilance for all the three components, information technology that would facilitate patient events, medical records, informed consent, and then increased clinical accountability.

The Strategic Plan should start with analysis, identify the issues, and branch off with strategic initiatives. It was pointed out that the title of the committee and make-up of the committee has not changed to reflect that change in the Charter. It is need to establish this as a priority of the strategic plan.

A comment was made to focus on safety. Dr. Klein spoke about stable and sustainable reimbursement. In the Secretary's Plan, there was something about changing the payment to be more focused on outcomes. The way of reimbursing for tissues, organs, and blood are totally different. Ms. Birkofer brought up the funding for Comparative Effectiveness Research that was provided in the Recovery Act, and asked if the committee would be willing to focus on outcomes and reimbursement, and access being based on clinical efficacy and not costs.

It seems there are two approaches here. One is to think about all the things the committee could do and that can be accomplished. The other is to look at the Secretary's Initiative and ask what is being funded and already on the priority list.

The following steps were stated: prioritize the issues that are coming up, categorize those as to where they would fit within the Secretary's Initiatives, and think about which of these topics the committee should address in future meetings. Another suggestion would be to bundle some issues such as product, patients, and funding. After some discussion, five items were brought forth: optimal blood management, pathogen reduction, biovigilance, risk-base decision-making, and wellness/prevention.

Committee Discussion Continued

The committee's job is not to be ultra comprehensive. The goal isn't to necessarily come up with every possible topic or issue that the department needs to be focused on, but instead try to bulk things into major categories. The highest impact and the highest priority is to come up with the three top priorities related to blood, the three top priorities for organs, and the three top priorities for tissues. The points and the goals at this point are to really focus in on priorities.

During the two day meeting, a number of experts in the field presented information that fostered a vigorous debate among Committee members and public members of the audience. After careful consideration of collective input, the Committee developed the following outline of key strategic priorities for blood, tissues, and organs safety, including cross-cutting priorities:

Blood Safety Priorities:

Patient Safety

- Promote and establish high value and effective evidence-based patient blood management

Product Safety

- Fund safety technology development and implementation (e.g., pathogen reduction technology and infectious disease/emerging infectious disease testing)
- Establish an evidence-based donor history questionnaire
- Fully reimburse costs of safety measures

Biovigilance

- Fully establish Biovigilance for blood donors and recipients to improve outcomes

Donor Wellness

- Promote and protect donor health

Risk Management

- Improve risk-based decision making and communication (e.g., informed consent)

Cell/Tissue Priorities:

Product Safety

- Determine the elements that contribute to product safety
- Assess the intrinsic quality of cell and tissue products
- Determine the optimal processing and testing of cells/tissues to mitigate disease transmission
- Establish an evidence-based donor history questionnaire

Patient Safety / Risk Management

- Improve risk-based decision making and communication for optimal tissue utilization (e.g., informed consent)

Biovigilance

- Establish Biovigilance for cell and tissue recipients to improve communication, traceability, and outcomes

Organs Priorities:

Product Safety

- Support the development of technologies for appropriate rapid screening of transmissible markers to quality organ availability
- Establish evidence-based donor history questionnaire

Patient Safety / Risk Management

- Improve risk-based decision making and communication for optimal patient management (e.g., informed consent)

Biovigilance

- Establish Biovigilance for organ recipients to improve communication, traceability, and outcomes

Cross-cutting Priorities:

- Improve flexible funding mechanisms for emerging public health priorities
- Increase public awareness of issues affecting the safety and availability of blood, cells, tissues, and organs
- Support International Collaborations that additionally leverage international experience

A motion was made to vote on the current blood cell, tissue, and organ priority and language. The vote passed unanimously.

Next Steps and Committee Discussion: Following the votes, it was noted that the Advisory Committee could engage in discussions of prioritization in the near future and map them in alignment with the Secretary's Strategic Plan. Part of the follow-up is to put meat on the bones in the important areas. It was suggested taking the information back to the BOTSEC and then bring it back for the Advisory Committee for comment. Finally, forward it to the Blood, Organ, and Tissue Senior Executive Council for final approval.

Dr. Ison thanked Renee and Jerry for organizing the meeting and the audio and video staff for the camera and the microphones. Lastly, he thanked the committee for all of their time, effort, and discussion.

Adjournment