Summary of
Advisory Committee on Blood Safety and Availability,
Department of Health and Human Services

Wednesday August 30, 2006

The meeting was called to order at 9:00am by the Chairman, Dr. Arthur W. Bracey, MD and a roll call was held. A quorum being present, the Committee's Executive Secretary, Dr. Jerry Holmberg began the proceedings by addressing issues related to conflict of interest, up-coming meetings of various organizations and payment of honoraria and travel expenses. He then turned the meeting over to the Chair.

After a brief statement regarding the drafting of a strategic blood action plan Dr. Bracey called for an up-date from Dr. Sanji Kumar of the FDA on the recently held Workshop on Malaria and Geographic Deferrals. He presented a brief overview of the epidemiology of malaria and a discussion of the FDA's current travel deferrals followed by further discussion on malaria testing. Dr. Kumar then gave a review of the workshop and the lessons the FDA learned from it. Several committee members had questions of Dr. Kumar regarding deferral policies. Dr. Sayers was concerned about blanket geographic deferrals as they disadvantaged states proximal to Mexico where many of the potential donor pool vacation and suggested the potential benefit of on-the-spot testing of donors. There was additional discussion regarding pathogen reduction and how it is not practical to use the current technologies.

The next speaker was Dr. Lou Katz, the executive vice president of the Mississippi Valley Regional Blood Center, who spoke on the work that the AABB has done on pandemic preparedness. He discussed the various models for dealing with a pandemic and the assumptions upon which they are based. The key elements of responding to a pandemic, in his opinion were vaccine and antiviral priorities, operational continuity, work rules, triage, social distancing, recruitment of recovered donors, and supply chain integrity among others. He also mentioned the cost effectiveness of preparedness and referenced the New Orleans disaster about the relative efficiency of preparedness. Following his presentation several members of the committee made comments supporting the work of Dr. Katz and his work group.

Following the discussion with Dr. Katz and follow-up discussion with Dr. Kumar the meeting was opened to public comment. The first to be heard from was Ms Marcia Boyle, president of the Immune Deficiency Foundation, who provided an over-view of the Immune Globulin, Intravenous (IGIV) situation and called for equity in Medicare reimbursement. Ms Courtney Yohe, the grassroots coordinator for the Public Health Pharmacy Coalition, spoke next, following a brief recess. She also spoke to the issue of IGIV availability and urged the Office of Pharmacy Affairs to take affirmative steps to assure that Public Health Act Section 340B providers would continue to have access to IGIV. Following discussion related to whether a real shortage of IGIV existed Ms Melissa Schweitzer of the IGIV Access Coalition spoke about her coalition's common goal of improving access to IGIV through improved reimbursement by CMS.

The next order of business for the Committee for the remainder of the meeting was the topic of biovigilance. Dr. Bracey posed a series of questions and topics for deliberation. The first topic was that of definition; that is, what are the essential components of a biovigilance system? Should biovigilance be considered a part of a comprehensive quality standard as expressed in CGMP, CGTP or CLIA? What are the characteristics of a biovigilance system that are already in place in the United States? What is the role of the Federal government and the private sector in a biovigilance system?

In response to these broad questions, the first speaker was Dr. Matt Kuehnert who reviewed the discussion from the last meeting. He discussed his particular working group that began its efforts with trying to reach consensus on a definition of the word, biovigilance and what that definition would encompass. It was his opinion that biovigilance should consider three main components; donor surveillance, recipient surveillance and monitoring of events with some type of error detection incorporated into it. A great deal of discussion resulted from the issue of error reporting and methods to get organizations to report errors without somehow negatively effecting their reputations in the community in which they serve.

Ms. Mary Malarkey, the Director of the Office of Compliance and Biologics Quality at CBER, delivered a presentation on biovigilance as a quality system. She said that the main principle of a basic quality system is the prevention of quality defects before they occur. Specific to blood, this involves proper donor screening, validation of the manufacturing process, detection and deviation reports, auditing those reports, and correction. There was no discussion following her presentation.

The next speaker was Dr. Laurence Sherman, Professor Emeritus from Northwestern University and assessor with the Joint Commission for Accreditation of Healthcare Organizations (presently known as The Joint Commission), who spoke on some of the aspects of what the Joint Commission's role was in regard to accreditation and then focused on the relationship of blood to tissues and also organ transplantation. He reviewed the history of JACHO as a means to improving quality in hospitals. The method by which an organization becomes accredited was also reviewed. Dr. Sherman discussed quality benchmarks for blood transfusion and tissue transplantation and what constitutes a reportable adverse event. He indicated that the Joint Commission, in regard to blood, is continuing to develop and adopt changes that look at improving patient safety and that the Joint Commission would appreciate conclusion and recommendations from this Committee.

Following the lunch break the Committee heard from Dr. Robert Pinner, the Acting Director of the Coordinating Center for Infectious Diseases of the CDC, who spoke in general terms about public health surveillance and its relationship to quality assurance on production and the distribution process. He observed that surveillance, in and of itself, doesn't tell a very good story. The issue, he said, is how questions are framed and what is counted and why. Also important is where the threshold is set so as to avoid the waste of resources when the threshold is too low vs. having the threshold too specific and too high thereby not responding at all until the phenomenon was about to go away, anyway.

Representing Public Health Agency of Canada, Ms Nancy McCombie, a senior program consultant for the Transfusion Injury Section of the Blood Safety Surveillance and Health Care Professions Division, spoke on the Canadian hemovigilance system. She began her talk with an explanation of where her Division fits in the overall Public Health Agency and where that fits in the Canadian government. She then discussed the surveillance systems that are present to examine transfusion-transmitted injury. These systems capture data on moderate to severe adverse events which are used to perform analysis to determine the risks of blood transfusion. She also discussed Canada's voluntary, non-punitive and non-nominal transfusion error surveillance system and the manpower required.

Dr Jeanne Linden, a former member of the Committee and Director of Resources for the State of New York Health Department, was next to speak. Her talk was about two issues; event reporting specifically related to transfusion transmitted infections and hospital-acquired infections. She discussed reporting related to these issues and recommended that when designing any reporting system it must consider the entire system and all the players in it. She further stated that if one wants to improve and prevent one must look at root causes. Also desirable is a set of standardized definitions and have those doing the reporting recognize the value of the system. Any information based on the system should only be released in an aggregate form so that individual entities can not be recognized. Following her presentation there was considerable discussion regarding the New York reporting experience.

Dr. Ruth Solomon from the Office of Cell Tissue and Gene Therapy of the FDA spoke on the tissue safety team as an example of a coordinated effort to deal with adverse reactions related to tissue transplantation. She explained why the team was formed, gave some background information on tissue regulation, and discussed the present and proposed accomplishments of the team. Her talk was followed by the afternoon break.

Upon resumption, the Committee heard a comment from Mr. Dave Cavanaugh of the Committee of Ten Thousand. The remainder of the afternoon was spent in a rather vigorous discussion related to data gathering, the setting of bench mark and initiation of any vigilance system. The meeting adjourned at 5:50 p.m.

Thursday, August 31, 2006

The meeting was reconvened at 9:00 a.m. and the roll called. Determining that a quorum was present, the Chair introduced the first speaker of the day, Dr. Barbee Whitaker, the Director of Data and Special Project for the AABB. Dr. Whitaker began her talk with how the AABB defines biovigilance. It is the detection, gathering and analysis of information regarding the untoward and unexpected events of transfusion and transplantation of cells, tissues and organs. The thrust of her talk, however, was related to adverse transfusion events. She proposed a task force that would come together to work toward further defining biovigilance and outlined objectives for this task force. Her talk was well received and a great deal of very positive discussion was generated.

The second speaker of the day was Dr. Susan Rossman, the Chief Medical Officer of the Gulf Coast Regional Blood Center in Houston and who represented the views of America's Blood Centers. She presented the views of the ABC which are that hemovigilance should address donors and adverse reactions. It was her opinion that ABC could and should be an advocate for the donor and that ABC should do everything possible to keep the donor safe as well as the recipient. She discussed the gathering of data, the utility of the data and the burden on the individual blood center of reporting the data. The success of a biovigilance program depends on the definition of the data and participation. She pledged cooperation with any task force organized by the AABB and stated that ABC would be developing its own data collection system. During the discussion following her talk she indicated that, while ABC was in the planning stages of collecting data, the elements were not yet defined but it would be a system that represented what they could influence.

The next speaker was Dr. Anne Eder, the Executive Medical Officer for the American Red Cross. She emphasized the ARC supports donor safety being addressed by a biovigilance program. The goal of ARC's surveillance program is to improve blood safety for recipients, minimize this procedure risk for donors, and detect significant trends that emerge from analysis of reports of rare events. The scope of data collected by the program encompasses donor reactions and injuries and recipient complications. She discussed the hemovigilance efforts being undertaken by the Red Cross and explained what it has learned from the data it has gathered. She indicated that data properly gathered and analyzed can certainly improve outcomes. Dr. Eder gave a snapshot of complications reported in 2005. Transfusion related acute lung injury (TRALI) accounted for the most reported non-infectious adverse outcomes. Septic reactions accounted for the second highest number of adverse reaction reports. Analysis of adverse events by components indicates that TRALI is associated with FFP and septic reports linked to transfusion of apheresis platelets linked to two arm procedures.

Following a discussion of the data of Red Cross, the topic shifted somewhat with the presentation of Ms Sharon Vernon, who represented HemoConcepts, a corporate entity engaged in promoting blood conservation. She discussed the overall state of blood supply vs. demand in the United States today and reviewed negative transfusion related outcomes. She then presented means by which blood conservation can be practiced and the advantages gained. The discussion following Ms Vernon's included the need for controlled studies, methodology for decreased utilization, and buy-in from hospital administration.

At this time, Dr. Agwunobi, the new Assistant Secretary for Health, arrived and addressed the Committee. During his address he stated, following a question from Dr. Sandler, that he was, indeed, the national blood safety officer and that when hard decisions regarding blood were to be made, those decisions would be his. He then thanked the Committee for all of its good efforts and presented service plaques to the members of the Committee whose terms were expiring.

A recess was taken after Dr. Agwunobi distributed the plaques and when the Committee reconvened it heard again from Dr. Whitaker speaking, this time, on the AABB West Nile Virus Biovigilance Network. She stated that the network currently consists of 45 testing laboratories and they have reported (at the time of this presentation) 171 confirmed positive cases with another 105 pending confirmation. She discussed how the network functions, the type of data that it collects and the intelligence the data provides.

Dr. Michael Soucie, from the Division of Hereditary Blood Disorders of the CDC, was the next speaker and he discussed its surveillance system monitoring the health and infectious disease status of end users of certain blood and blood products. The system or network tracks anyone who has a congenital deficiency of any of the clotting factor proteins below 50% of normal and is being followed by 135 specialized hemophilia treatment centers in the United States. The system collects not only data but blood samples and stores them for future testing. One of the results of the monitoring process the CDC has determined that there have been no new cases of hepatitis A, B or C or HIV as a result of blood or blood product exposure. Following his prepared comments Dr. Soucie took questions from Committee members as well as members of the general audience and following that, the meeting adjourned for lunch.

Upon resumption after lunch the Committee heard from Theresa Horan who is the surveillance coordinator for the Infection Surveillance Program of the National Healthcare Safety Network (NHSN). She began with a brief history of infection control and then explained the purpose and processes of the program. During the presentation she demonstrated how the NHSN could be used with a blood bank specific module.

Dr. Harold Kaplan, Professor of Clinical Pathology at Columbia University Medical Center, was the final scheduled speaker of the meeting. He spoke on MERS-TM, the program developed for error reporting in transfusion medicine. MERS-TM has events classified into three categories; events with harm, events without harm or near misses and recovery, and an area that has not had enough scrutiny. He talked about near miss reporting and its advantages; it focuses attention toward what causes events with harm before the harm occurs. He indicated that several countries such as the U.K, and Croatia aggressively report near misses and those reports, among others, indicate a yield predicted by Robert Heimreich that for every major injury there are 29-30 minor injuries and 300 non-injury events. An important issue with safety, he said, isn't so much what caused the event but what the consequences were to the patient, what factors affected the consequences and what are the latent errors or failures that are going into the system. Safety is an on-going effort; safety is not bankable.

Almost immediately following Dr. Kaplan's presentation and subsequent question and answer session, Dr. Kuehnert and Dr. Bracey proposed two similar but slightly different versions of the same recommendation.

The Committee discussed at considerable length both versions, merged them into a single statement and then fine tuned the language. The Committee's unanimous recommendation to the Secretary is as follows:

Whereas, promoting the safety of the U.S. blood supply is a principal activity of the Advisory Committee on Blood Safety and Availability, and inclusion of efforts to improve organ and other tissue safety and availability also need to be considered, we recommend that the Secretary coordinate federal actions and programs to support and facilitate biovigilance in partnership with initiatives in the private sector.

Biovigilance is defined as a comprehensive and integrated national safety program to collect, analyze, and report on the outcomes of collection and transfusion and/or transplantation of blood components and derivatives, cells, tissues, and organs.

The program should be outcome-driven, with the objectives of providing early warning systems of safety issues, exchanging of information, and promoting education and the application of evidence for practice improvement.

Formation of a PHS Biovigilance Task Group, including the Assistant Secretary and representatives of PHS agencies, would be an important initial first step for identification of the vision, goals, and processes needed to advance these objectives.

This Task Group is needed to participate with private-sector efforts, including the AABB Interorganizational Task Force on Biovigilance, to advance public health in this effort. The PHS Task Group should produce an analysis and operational proposal, concurrently with the AABB Interorganizational Task Force on Biovigilance and other private-sector efforts, to include a gap analysis regarding the effectiveness of the current system, the need for mandatory versus non-mandatory and regulatory versus non-regulatory reporting, the scope of reporting with regard to product problems, medical errors, and clinical adverse events, including recognized and novel events; database centralization versus data sharing, database governance, ownership, and accessibility, format and standards for data reporting, including confidentiality; funding mechanisms for a sustainable system, and design and feasibility of suitable pilot programs to determine the characteristics of a value-added system.

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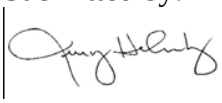

Jerry A. Holmberg, Ph.D.
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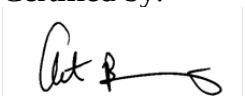

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