Advisory Committee on Blood Safety and Availability
Department of Health and Human Services
26th Meeting Minutes
May 16 & 17, 2005

The 26th meeting of the Advisory Committee on Blood Safety and Availability was called to order at 9:00 AM by the Executive Secretary, Dr. Jerry Holmberg. Dr. Holmberg introduced two new members of the Committee: Dr Arthur Bracey and Dr. Susan Roseff. Another new member, Dr. Pearl Toy was unable to make the meeting.

I. Administrative
   a. Members Present: Judy Angelbeck, PhD, Celso Bianco, MD, Mark Brecher, MD, Paul Haas, PhD, Andrew Heaton, MD, Jeanne Linden, MD, MPH, Karen Shoos Lipton, JD, Gargi Pahuja, JD, Susan Roseff, MD, S. Gerald Sandler, MD, Merlyn Sayers, MD, PhD, Mark Skinner, JD, John Walsh, Wing Yen Wong, MD; Non-Voting Members: James Bowman, MD, CMS, Jay Epstein, MD, FDA, Michael Libby, CDR, MSC, USN DoD, Matthew Kuehnert, MD
   b. The meeting was turned over to Dr. Mark Brecher who summarized that three recommendations had been sent forward to the Secretary from the January meeting.
      i. Bacterial blood safety initiative
      ii. Reimbursement of plasma-derived products and their recombinant analogs
      iii. Financial burden for patients with bleeding disorders

II. Committee Updates
   a. Dr. Dorothy Scott presented an update on the recent workshop on Intravenous Immune Globulin (IGIV) in the 21st Century: Progress and Challenges in the Efficacy, Safety and Paths to Licensure. The goals of the workshop were to discuss the current issues in the efficacy and safety of immune globulins; and to examine and analyze the results of FDA's 1999 paradigm for IGIV licensure.
      i. Dr. Scott reported that subcutaneous immune globulin is currently being studied for use in primary immune deficient (PID) patients in a similar fashion in which IGIV is used but may have some special advantages for some patients.
      ii. Unresolved issues
         1. Best dosing for infection prevention has not been defined on an individual basis, that is, the frequency and amount of IGIV needed for a particular patient.
         2. Monitoring and the markers used remain controversial. Surrogate markers were proposed by Dr. Stiehm
            a. Trough IgG levels
            b. Antibody titers to important pathogens
            c. Pulmonary function test

d. Acute Phase reactants

3. Clinical outcome measures are also controversial since most IGIV studies usually involve about 40-60 patients.
    a. Infections frequency is important and is an endpoint of most pivotal trials
    b. Pulmonary function is believed to be a long-term measure of outcome since many pulmonary infections lead to end-organ damage.
    c. Frequency of antibiotic use
    d. These outcomes can not be easily measured in one-year clinical trials
    e. Can clinical trials be shortened and could surrogate markers be used?
4. Infections in patients that are already receiving IGIV and the understanding of the natural history of people with primary immune deficiency treated with IGIV is not complete. End-organ damage probably increases the infection rate in IGIV-treated patients. The unresolved issue of how can their treatment be improved and what can be done to treat patients who already have fixed end-organ damage.
5. Care of PID patients with chronic infections was also discussed. A question was raised in the workshop if IGIV with selected high titers to pathogens be used along with monoclonal antibodies.

iii. Early diagnosis of PID is needed in order to prevent end-organ damage. One of the workshop speakers, Dr. Buckley, proposed that screening occur at birth.

iv. Titers of antibodies to varicella and measles are going down in IGIV. An IGIV repository was proposed for research purposes.

v. A working group was formed from the workshop participants. This working group will assess:
    1. the association of dose and trough levels with clinical outcomes over long periods of time.
    2. the optimization of treatment in people with end-organ disease who aren't necessarily often studied in clinical trials.
    3. the validation of surrogate markers of efficacy.

vi. Safety issues related to IGIV were also discussed. It was discussed that adverse event labeling is difficult to compare among products and that a standardized ascertainment of adverse events over clinical trials would be useful. There is interest by the workshop participants that post-marketing adverse event rates should be monitored. Models of surveillance for adverse event reporting was also presented and discussed.

vii. From 1996 to 2002, no new IGIV products were licensed. In 1999 FDA proposed a paradigm for licensure that was more streamlined. Since 1999, four new products have been licensed.

b. Update on IGIV Supply and Reimbursement

i. Patrick Schmidt, President and CEO of FFF Enterprises, addressed the Committee on the current status of IGIV availability. This year FFF will distribute in excess of eight million grams of IGIV and four million equivalent units of human serum album. Mr. Schmidt stated that evidence supports that it is becoming more difficult to obtain IGIV at affordable prices. There is a new market reality, fewer supplies and rising prices. Healthcare providers who treat Medicare Part B beneficiaries are finding it virtually impossible to obtain IGIV prices conducive to continuity of care.

1. Three reasons:
    a. Modest price increases by the manufacturers,
    b. Implementation of average sales price (ASP) plus six per cent reimbursement methodology, and
    c. Increasing evidence of opportunistic pricing practices of the secondary channel distributors.
2. In May 2003, FFF had approximately 1.6 million grams of IGIV in inventory. Today the inventory has tightened to around half a million grams of inventory in stock. According to Mr. Schmidt there is virtually no slack in the system and the market place is dependent on timely lot releases and shipments.
3. Due to the tightening market, Mr. Schmidt reported that the companies have implemented allocation systems. Today FFF has less than 30 days of supply on hand.
4. Mr. Schmidt stated that the secondary channel's action is indicative of the overall supply situation. The secondary distributors are a constant, destabilizing influence in the IGIV market. He estimates that 24 per cent of the nation's supply (6 million grams per year) is vulnerable to the pricing practices of the open market or spot market.

ii. Discussion turned to the FDA's role to provide education in the safe and appropriate use of albumin. Dr. Epstein stated that after the publication of the Cochrane report on albumin safety in the British Journal of Medicine, the FDA posted a web notice. Since that time, there has been criticism of the meta-analysis that was in the Cochrane report and an Australian study, SAFE, which did not find safety problems with albumin, except for a potential caveat about concomitant brain injury. During the meeting the FDA posted a revised web notice recognizing the more recent data for the use of albumin and reversed the previous thinking on its use.

iii. Ms Julie Birkhofer of the Plasma Protein Therapeutic Association addressed the Committee on the issue of IGIV supply and

reimbursement. She stated that the CMS, ASP plus 6 percent does not reflect a dynamic market. Supplies as reported by PPTA members indicate a status of "yellow," which indicates approximately one month supply (4-6 weeks) and this does not support a shortage scenario. Companies have responded by increasing supply to meet demand. Ms. Birkhofer stated that CMS response to separate codes for liquid and lyophilized forms of IVIG was only a band-aid and did not correct the problem. PPTA would prefer that the separate codes be given to individual therapeutic products and not be bundled together.

iv. Ms. Amy Bassano of the Centers for Medicare and Medicaid Services addressed the Committee. Medicare Part B has limited drug benefits and only covers approximately 450 drugs that Medicare reimburses. These are oncology drugs and other drugs furnished in the physician office. Blood products and other blood clotting factors are excluded from Average Sales Price and continue to be paid under the average wholesale price. Clotting factors are also paid based on furnishing fee that is 14 cents per unit. Beneficiaries may call 1-800-Medicare to report problem with access to a product through a regional office.

v. Open Public Comment

1. Ms. Michelle Vogel, Immune Deficiency Foundation, mentioned that they have received over 300 calls complaining that the Medicare patients cannot receive their IVIG infusions at their physicians' offices, outpatient infusion centers or home care settings, or evening in the hospitals at this point. Some patients have been shifted to the hospitals and have been admitted for 23 hours for their infusions. Ms Vogel mentioned that 95 percent Average wholesale price (AWP) is too high but something needs to be done to correct the reimbursement rate and suggested 83 percent AWP.
2. Mr. Larkin of the Greater New York Hospital Association commented to the Committee. He mentioned that every one of his members has experienced product shortages and that they are all on product allocation.
3. Ms Schweitzer, Director of Patient Advocacy for the Immune Deficiency Foundation spoke. She related that patients are having difficulty getting infusions in physicians' offices.
4. Mr. Stein of the American Society of Health system Pharmacists addressed the Committee. The ASHP have seen with other drugs that when the grey market secondary and tertiary suppliers get into the distribution mix, there are problems with diverted drugs, counterfeit products and

because of storage conditions necessary to protect products they have seen significant safety concerns.

5. Mrs. Marcia Boyle, Chairman, CEO and founder of the Immune Deficiency Foundation spoke. IDF will immediately begin surveying the Medicare patients and physicians who treat the IDF community to assess the impact of reimbursement on access to care. She went on to state that a public health crisis has been created and patients are suffering unnecessarily.
6. Mr Donohue, a patient with chronic immune demyelinating polyneuropathy and a chronic immune deficiency. Infusions of IVIG have helped his condition; however, in 2005, the reimbursement formula interrupted his prescribed treatment schedule.
7. Dr. Davis-Fuji, a neuromuscular specialist in private practice and on faculty at UTMB in Texas addressed the Committee. He mentioned that nurses in the hospitals do not know how to administer the drug and that all IVIG products are not the same.
8. Dr. Fuji's patient with Myositis mentioned that she will die without IVIG.
9. Spokesperson for Committee of 10,000 spoke. He mentioned that the gains made in the 1990's are being eroded. He went on to say that the Committee needs to reinvigorate itself and be aggressive about the federal response which is what the IOM recommendations were all about.
10. President of PPTA commented that the reimbursement issue is causing tremendous problems and is putting the health of patients at risk. Consolidation of the plasma industry and movement of companies' fractionation plants to other parts of the world. This is viewed as a positive event since better technologies are being employed to produce higher yields.
11. Dr. Draker addressed the Committee and stated that he was anger that he became a physician to care for people, not to be handcuffed by bureaucracy. Over the last two weeks, Dr. Draker has made calls to senators and congressmen but has not received any response on this issue.
12. Committee Discussion on IGIV:
    a. Dr. Brecher challenged the Committee with a question, "So the question is what can we as an advisory committee to the Secretary of Health and the Assistant recommend to try to fix this problem?" The Committee is still waiting for a

response about reimbursement for plasma-derived products and recombinant analogs.

b. Dr. Bracey suggested that a public health emergency may be necessary.
c. Dr. Bianco summed up the difficult morning in that the Committee heard from the outside. The presentations from:
    i. Patients were really very touching
    ii. Manufacturers have issues in terms of manufacturing and having to make a profit.
    iii. Distributors represent both primary and secondary. The Committee only heard from a primary distributor.
    iv. Pharmacist
    v. CMS stuck to a law that doesn't seem to be responding to those needs of the patient.
d. Ms Vogel clarified for the Committee that CMS is willing to do a demonstration project. Increasing administration reimbursement of IGIV as a biological response modulator may be an option.
e. After much discussion, the Committee postponed further discussion until later and adjourned to lunch.

vi. Recommendation (Passed 12 in favor, none opposed, no abstention) : The Committee finds that:
    1. Since our prior recommendations of January 2005, there is a worsening crisis in the availability of and access to IGIV products that is affecting and placing patients' lives at risk (e.g., patients with immunodeficiency).
    2. Changes in reimbursement of IGIV products under MMA since January 2005 have resulted in shortfalls in the reimbursement of IGIV products and their administration.
    3. Immediate interventions are needed to protect patients' lives and health.

    We therefore urge the Secretary:
    1. to declare a public health emergency so as to enable CMS to apply alternative mechanisms for determination of the reimbursement schedule for IGIV products, and
    2. otherwise to assist CMS to identify effective short and long term solutions to the problem of unavailability of and access to IGIV products in all settings.

III. Strategic Actions for Emerging Infectious Diseases to Reduce the Risk of Transfusion Transmitted Diseases and its Impact on Availability
    a. Dr. Linden presented a review of the discussion of the January 2005 meeting.

i. Coordination is needed for coordinated public health response within agencies, among federal agencies and other partners, including coordination with stated agencies and other countries because of many of the global issues
ii. Effective surveillance is needed to monitor new agents as they start to emerge, and the emergence known agents or those previously identified but changing, as well as agents that are not presently sufficiently addressed, such as Chagas disease.
iii. Phase 4 surveillance that assesses the impact of new products and their safety profiles is important.
iv. Prioritization of issues is important to identify research, resources and funding.
v. Risk communication was another issue for getting the information to physicians and recipients and potential recipients. Transparency of communication is critical, especially in timeliness, and when insufficient scientific data are known or unknown.
vi. Technology development and incentives that could help drive the development for diagnosis; identification of the diseases as well as potentially pathogen reduction came up as issues.
vii. Discussion also included a need for a flexible process, especially when there is scientific uncertainty. A general framework but a flexible process that could be tailored to a specific situation.
viii. Overall the general discussion was a need to develop a coherent approach, utilizing all the available resources and the strengths of the different agencies and organizations and players in a coordinated way, building on the strength of those partners.

b. Dr. Benjamin Schwartz, senior scientific advisor to the National Vaccine Program Office within the Office of Public Health and Science presented the HHS Pandemic Action Plan. Dr. Schwartz mentioned that we don't know when a pandemic will occur but certainly planning and preparedness are important so that when it does occur we are ready.
i. As of mid-April of this year, a total of 88 human cases of H5N1 influenza have been identified, of which 51, or 58 per cent, had ended fatally. Clearly, our surveillance is detecting the most severe cases and we don't expect that this 58 percent case fatality rate is the true case fatality rate of all H5N1 infections.
ii. For a pandemic to occur it would require that this avaian strain either mutates or resorts with the human strain and, therefore, acquires the ability to be transmitted between people. For example, several years ago there was an outbreak of avian H7N7 influenza in The Netherlands with associated human cases, and in 2003 there was a H7N3 outbreak in British Columbia.
iii. HHS goal is to finalize the 2004 draft plan by this summer.
iv. In a pandemic it is likely that influenza vaccine supply will be a problem. We assume that imported vaccine will not be available

since countries' that manufacturer vaccine will retain whatever product in that country to protect their own population.

v. Two doses of vaccine will be needed for protection to a strain which nobody has had prior experience with.
vi. Defined groups to receive to early vaccine supplies will need to be identified.
vii. Antiviral drugs may be an alternative in the beginning of a pandemic.
viii. Duration of illness generally is 5-7 days, with additional time required for recovery. Illness tends to be characterized by fever, which is one of the first symptoms, malaise, myalgias and respiratory symptoms which generally only occur later. Viral shedding occurs one day before symptom onset and some people have infection which is asymptomatic throughout its duration. With respect to blood safety, it is unlikely that safety will be affected in part because influenza associated viremia appear to be uncommon, and primarily because if viremia does occur it will be associated with fever and severe illness so that it is unlikely that these folks are going to want to donate. There will probably be a decrease in elective surgeries and the need for blood will drop.
ix. In summary, in a pandemic there will be a decrease in the blood supply, there will be a decrease in the demand for blood and also a decrease in blood drawing capacity. There should be little impact on the safety of the blood supply.
x. Ms Lipton raised a question on the identification of blood center workers who should be identified in the priority groups for immunization. Dr. Swartz mentioned that both the Advisory Committee on Immunizations Practices and the National Vaccine Advisory Committee ware making recommendations for priority groups in a public forum in June or mid-July. He encouraged Ms. Lipton to share thoughts with the advisory committees before then so that they may be considered in the deliberations.

c. Dr. Fernando Guerra, Director of Health and Director of Center for Environmental Health for the San Antonio Metropolitan Health District represented the National Association of County and City Health Officials.
i. Local public health monitors on an ongoing basis the overall health status and specifically investigates health problems in the community whether it is an outbreak of flu, respiratory illnesses or food-borne illness, or something that puts the population at risk.
ii. Communication and coordination is important.
iii. Local public health officials have another role in being able to map out the clustering and/or the observations that are made where there might be certain diseases.
iv. Population demographics are important, especially border location, refugee population and access to international flights.

d. Dr. Richard Raymond, Director of Department of Health and Human Services, Regulation and Licensure, Nebraska Health and Human Services System. He is President of the Association of State and Territorial Health Officials. ASTHO represents 50 states and 6 territories, including the District of Columbia.
    i. ASTHO will assume a major role, at any time emerging new infectious disease might be recognized.
    ii. Sharing of information is vital to a response to public health emergencies, and Dr. Raymond would suggest that this sharing of information needs to begin now, and not until pandemic influenza or the next infectious disease outbreak that we h ad not anticipated.
    iii. Since September 11th and the anthrax attacks, State and Territories have been receiving a large amount of information from the federal government on an annual basis to help prepare for public health emergencies. Public health laboratories are better equipped and the response time has been cut manifold by the health network system.
    iv. Public communication and education of the public is something that cannot be overlooked.
    v. Disruption of life and services will be an obvious outcome of the pandemic flu.
    vi. Dr. Raymond recommended that community blood centers need representation on state planning committees. There needs to be a unified voice for blood.
    vii. There is a need to continue to support state and local epidemiology laboratory infrastructure.
    viii. TopOff exercises are very important.
e. Dr. Alfred DeMaria, Chief Medical Officer, Director of the Bureau of Communicable Disease Control and State Epidemiology with the Massachusetts Department of Public Health. Dr. DeMaria represented the state epidemiologist, the Council of State and Territorial Epidemiologist which was founded in 1951 and serves the function of making recommendations to the Centers for Diseases Control and Prevention (CDC) about diseases that should be reportable or how they should be reportable and how surveillance should be accomplished.
    i. To state epidemiologists the important issues are disease reporting of reportable diseases.
    ii. Reporting clusters and outbreaks.
    iii. The average public health worker knows little about blood collections, blood banking, screening and all the aspects of testing.
f. Discussion turned to “Models for Disease Reporting and Adverse Event Surveillance Universal Data Collection”
    i. Dr. Michael Soucie, CDC, reported on the Universal Data Collection system mandated and funded by Congress that arose from response to the bleeding disorders community. Data collection is coordinated with 135 hemophilia treatment centers.

ii. MS Teresa Horan, CDC, reported on the possibility for a national surveillance for transfusion-related adverse events in the context of the surveillance system that is located within the Division of Healthcare Quality Promotions in the National Center for Infectious Diseases.
iii. Dr. Theresa Smith, CDC, presented an overview of the ArboNET system used in West Nile reporting from the blood suppliers.
iv. Dr. Robert Wise, FDA addressed the Committee to discuss the safety surveillance system for blood and blood products. The system includes death reporting in donors or recipients, product failures, device malfunctions, adverse events in product recipients, and medical errors.
v. General consensus from the Committee was expressed by Dr. Brecher in that currently in the United States we have a fragmented system of surveillance. A comprehensive system is needed.
vi. Dr. Epstein focused the Committee attention to the fact that other countries measure the known and we have two different issues going, one is tracking and trending events, and the other is detecting and responding to new events.

g. National Heart Lung, Blood Institute's funded REDS II Program: Understanding the REDS II Program and its Role in Detecting Emerging Threats.
    i. On the second day of the meeting, Dr. Michael Busch of Blood Systems Research Institute, reported on the activities of the REDS II Program.
        1. Over the last several decades, NHLBI has made great efforts to establish donor-recipient repositories to allow the blood community to establish prevalence of the emerging agents in the donor pool. And to link donor-recipients to track transmission. Not only transmission but the rate of transmission of agents can be established.
            a. The FACTS study, which was the Hopkins Houston Cardiac Surgery Cohort. Most recently HHV-8 transmission was reported in Transfusion. Unfortunately the study did not have donor samples and only reported recipient population results.
            b. REDS repositories which are donor repositories
                i. Donor REDS
                ii. General Leukocyte Plasma Repository (GLPR).
            c. RADAR Repository
        2. Value obtained from these repositories include:
            a. Publications
            b. Data presentation at meetings
            c. Policy decision making.
    ii. Orphan Test Development

1. Dr. Ortolano of Pall Biomedical addressed the Committee on the development of prion filtration as an orphan test.
    a. Filtration proposed by Pall Biomedical reduces all prions tested, both cell and non-cell associated.
    b. This methodology may address the risk of prior transmission which is associated with vCJD.
2. Dr. Robert Rowher from the VA in Baltimore and the University of Maryland addressed the issue of "Removal of TSE Infectivity from Blood and Blood Products by Adsorption.
    a. Dr. Rowher founded his company because he had a very strong opinion that removal was probably the only thing that was going to work in terms of mitigating the risk of transmission of disease by blood. They attracted the American Red Cross and Prometic Corporation.
    b. Methods available could include:
        i. Screening
        ii. Inactivation
        iii. Ligand removal
3. Dr. Alan Rudolph from Adlyfe, Inc presented their PrP-Sc detection method.. Although their system is hopeful, Dr. Rudolph recognized the importance of high-throughput kits for the blood community.
4. Dr. Stuart Wilson from Microsens, UK presented their method to detect protein conformational disorders. They have detected the prion protein in the blood of symptomatic and asymptomatic scrapie infected sheep. It is a small-volume blood assay.
5. Dr. Lawrence Corash from Cerus Corporation discussed the status of pathogen reduction. He focused his attention on platelets because the general topic of pathogen inactivation was too broad for the current forum.
    a. Pathogen inactivation can be thought of as a prospective and complementary strategy to further improve and deal with some of the issues that have not been completely resolved. It would also interdict pathogens that are not currently tested and low-burden pathogens during window periods.
    b. Technology does not inactivate certain non-envelop viruses, the most notable being the hepatitis A virus that has an extremely tight protein capsid.
    c. Cerus technology was implemented into European clinical practice in 2003.
6. Dr. Sanjai Kumar, FDA, discussed orphan test development for malaria detection. Currently there is not approved test

that can be used in this country to screen for malaria parasites in donor blood. Possible screening methods include QBC, DNA-based test (PCR, TagMan, and real-time PCR) and microarray. The Europeans use ELISA.

7. Dr. Robert Duncan, FDA, reported on Chagas, leishmania, and bioterror agent detection.
8. Dr. Dimitra Georganopoulou, Northwestern University, discussed the application of nanotechnology to detect pathogens. In the last tree years, Dr. Chad Mirkin's group has developed a method called "Ultrasensitive Detection of DNA and Proteins" using nanopariticles.
9. Dr. Eric Delwart, Blood Systems Research Institute, spoke on "Detection of New Pathogens through Surveillance of Bank Samples."
    a. Dr. Delwart discussed ways to detect new agents, either emerging viruses, or viruses that have been present but not detected.
    b. Technologies use nucleic acid based. Approach can be shotgun sequencing or a narrow approach to discover anticipated viruses.

h. A recommendation was presented to the Committee and discussion followed. Much discussion involved the scope of the Committee and whether recommendations that went beyond blood, blood products, plasma products, and clotting factor analogs could be included. The Committee agreed, after lengthy discussion on a proposed recommendation, that there needed to be additional discussion at the next meeting. The recommendation was tabled and the subcommittee was charged with reviewing the transcripts from both the January and May 2005 meeting. Further discussion would take place by the subcommittee and reported back to the full committee in September.

IV. Update on Bacterial Detection Methodology and Methods for Release Platelet Concentrates.
    a. Chairman Brecher, because of his many research interests in bacteria and platelets, asked Mark Skinner, JD to preside over the next part of the meeting.
    b. Dr. Larry Dumont, Gambro BCT, provided a brief history on the 510(k) clearance that was recently obtained by Gambro BCT and highlight issues related to tow-bottle testing (i.e. aerobic and anaerobic), and to present Gambro BCT post marketing surveillance study.
        i. Gambro BCT is cleared for a seven-day platelet collection ELP bag, when it is coupled with a 100 percent screening for bacterial contamination prior to transfusion.
        ii. Final post marketing surveillance protocol was submitted and reviewed.

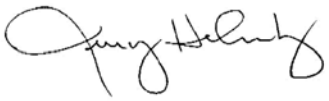
iii. Original submission made by Gambro was for aerobic testing system only. The FDA reviewed the data and concluded that the evidence did not support exclusion of the anaerobic bottle at this time.
iv. Specific aims of the post-marketing surveillance will be to determine the specificity, sensitivity, negative predicted value and positive predicted value of the two-bottle release test and determine the prevalence of bacterial contamination for untested and for two-bottle BactT/Alert tested single donor platelets.

c. Dr. Stein Holme, Pall BioMedical, updated the Committee on the Pall Bacterial Detection System, eBDS and seven days of storage as well as testing for pooled random donor both at five and seven days of storage.
d. Dr. Sherrill Slichter, Vice President of Research for the Puget Sound Blood Center updated the Committee on her work and work accomplished with Haemonetics.
    i. There are no established criteria in the US, as there is for red cells, for the criteria for platelet viability after extended storage.
    ii. Based on data presented, Dr. Slichter believes that apheresis platelets could be licensed for eight days without do additional studies in thrombocytopenic patients.
    iii. Dr. Slichter believes that pooled platelet concentrates can only be stored for seven days.
    iv. During storage, platelet recoveries are better maintained than platelet survivals. Acceptable storage times that meet patients' needs and maintain platelet availability are eight days for apheresis and seven days for platelet concentrates.
e. Dr. Jaroslav Vostal, FDA, presented FDA current views on approval or clearance of bacterial detection devices for platelet release test indications and also for the extension of platelet dating.
    i. Analytical sensitivity of the device must be defined. This is usually accomplished through spiking studies and based on this data, a decision for clearance as a quality control device could be determined.
    ii. With clearance as a quality control device, data could be collected to determine the true and false positive rate in a clinical setting. This then could be evaluated for clearance as a release test with a commitment to do a post-market study.
    iii. Post-market surveillance would require an aerobic and anaerobic detection from an early sampling, confirmed with an aerobic and anaerobic detection at outdate.
f. Dr. James AuBuchon, Medical Director at Dartmouth Hitchcock Medical Center, spoke during the public comment period. There are two thoughts in the community.
    i. Facilities committed to the continued use of whole blood-derived platelets

ii. Facilities which advocate that apheresis platelets are better than whole blood derived platelets. If one would project out the use of apheresis platelets, it would imply that apheresis platelets will be 100 percent by 2010.
iii. Both whole blood-derived and apheresis platelets have been found to be clinically efficacious for multiple decades. He urged the Committee and the blood community to keep the options open until the scientific community has clear evidence that one way is better than another.

V. The Committee adjourned at 4:35 PM.

Submitted by:



Jerry A. Holmberg, Ph.D.
Executive Secretary, Advisory Committee for Blood Safety and Availability

Certified by:

Mark E. Brecher, M.D.
Chairman, Advisory Committee for Blood Safety and Availability