

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

39th MEETING MINUTES

June 10 and 11, 2010

The Universities at Shady Grove
9630 Gudelsky Drive
Rockville, Maryland

Thursday, June 10, 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.

Charge to the Committee on Current High Risk Behavior Deferral Policy for Blood Donors

Dr. Howard Koh, Assistant Secretary for Health, was introduced to the committee by Dr. Holmberg, who then asked the committee members to introduce themselves. Dr. Koh proceeded to make a few opening remarks. The FDA plays a very important role in upholding safety and regulating blood and blood products. I am the Assistant Secretary for Health; a physician who is trained in multiple fields, including hematology; and also as a state health commissioner before coming into this post a year ago. Being part of this process has been a great honor and privilege for me. This is a critical meeting that we have today because this advisory committee always looks at issues of blood supply and blood safety, defines the public health parameters, and also looks at the societal factors. He stated the committee is reexamining the FDA policy which states that a man who has had sex with another man at any time since 1977 should be deferred indefinitely from donating blood. The FDA needs to hear from you whether the studies at the current time indicate and can support a policy change, or what studies need to be undertaken in the future to implement such a change in the future. Dr. Koh was asked to comment more about his statement with regard to the importance of having scientific and research deliberations before a policy is made. In answering, Dr. Koh replied all policies should be based on the best science available. Science evolves and changes so fast that it's critically important to review the cutting edge studies from this country and also overseas. Societal issues as well. Question posed by Dr. Holmberg: is there any consideration within the department to allow for FDA's blood product advisory committee to consider this issue in tandem, or after the ACBS site? Dr. Koh pointed out they are getting input from all sources, both outside the department and also inside the department.

Conflict of interest statement was read by Dr Holmberg

Roll Call: It is noted a quorum is present. Dr. Holmberg stated for the record Dr. Yomtavian is a voting member of the federal government, a regular government employee that is on the committee and has the ability to vote. Dr. Corash, in contrast to what was mentioned in the introductions, is voting member.

Charge to the Committee on Current High Risk Behavior Deferral Policy for Blood Donors

FDA's Policy on Blood Donor Deferral for MSM

Dr. Jay Epstein, Director of the Office of Blood Research and Evaluation, Center for Biologic Evaluation and Review for the FDA, was the first speaker introduced. His task was to set the stage for the committee's discussion by describing FDA's current policy on the deferral for males who have had sex with another man since 1977 and explain its rationale. The current HIV prevention policy calls for a deferral of men who have had sex with another man, even one time, since 1977. Deferral means an indefinite or lifetime for persons with evidence of HIV infection, intravenous drug users, and for men and women who have engaged in sex for money or drugs since 1977. There is a temporary deferral for persons who are believed to be at a secondary risk. Risks have been reduced by order of magnitude. Dr. Epstein explained the strategies through which FDA seeks to insure blood safety. First, is the concept of risk-based deferral. This avoids placing infectious units in inventory. If a donor has risk factors, then even before tests are positive, the donor can be deferred. The current risk of major viral infections from transfusion is extremely low, but despite safeguards, transmissions still occur including HIV. Emerging infectious diseases cannot be quantified. It is known that men who have sex with other men have a higher prevalence of many transfusion transmitted diseases, which coincidentally are sexually transmitted diseases or diseases of close or intimate contact including HIV, hepatitis B, CMV, and syphilis. The FDA considers only the risk to recipients from the prevalence and incidence of HIV and other infections in donors who might be unaware of their infection, which is science-based. There are other indefinite deferrals that are recommended based on risk: exposure or potential exposure to Mad Cow Disease, CJD, commercial sex work and intravenous drug use. Why indefinite versus temporary deferral? He said that it reflected of the relative impact on blood safety from persons with that underlying risk factor. Another issue is identifying men who had sex with men who may be at low or even no HIV or other TCID risks. The HIV risk and other STD risks among MSM are higher than for heterosexuals. Dr. Epstein observed the current laboratory tests for screening of donors are extremely sensitive and with current nucleic acid testing of the virus is in the realm of nine days. The FDA's mission is to assure the safety, purity, potency and availability of blood products given the safety of the blood recipient. Also the FDA does take into account the accumulating body of scientific information.

Human Cell, Tissue, and Cellular and Tissue-Based Product (HCT/P) Policy

The next speaker introduced by Dr. Holmberg was Dr. Melissa Greenwald, Chief of Human Tissues, Office of Cellular Tissue within the FDA. The FDA does regulate human cells, tissues, and cellular and tissue-based products, HCT/P. She gave some background to the committee and discussed in detail several factors involved in the donor screening process. There is donor screening with risk-based deferrals, but they are different than those that are used in blood donor. HCT/Ps are articles that are containing or consisting of human cells or tissues that are intended for implantation, transplantation, fusion, or transfer into human recipients. There are both living and deceased donors in the donor populations. Dr. Greenwald went through the donor eligibility regulations for cell and tissue donors. She then spoke about the uses of cells and tissues from donors when eligibility is either incomplete or ineligible. They use behavior-based screening criteria to reduce the risk of HIV, hepatitis B, and HCV transmission. The current policy is to

recommend cell and tissue donors not be eligible if they've engaged in MSM, injected drugs for non-medical reasons, if they have hemophilia and have received human derived clotting factor concentrates, if these people have engaged in sex for money or drugs – all within the preceding 5 years, or had sex in the preceding 12 months with any person described above, or any person who has HIV, hepatitis B, or clinically active hepatitis C.

Epidemiology of Transfusion Transmitted Diseases in Individuals Practicing High

Risk Behavior compared to the General Population

A Review of the Current Epidemiology of HIV

Dr. Amy Lansky, Deputy Director of Surveillance Epidemiology and Laboratory Science, the division of HIV/AIDS prevention at The National Center for HIV, STD and TB prevention at the CDC was introduced. She spoke about the current epidemiology of HIV infection in the United States. First, she stated the prevalence, the number of persons living with HIV infection. She listed several statistics and following are a few: MSM accounts for approximately 48% of persons living with HIV, infected through heterosexual contact account for 28%, injection drug users 19%, and men who have sex with men who also inject drugs is approximately 5%. The prevalence rates allow comparisons between groups. Dr. Lansky spoke of the concept of being unaware of an HIV infection, which can be looked at this in three different ways. First, is the proportion of undiagnosed infection. Next, is the HIV testing behaviors. Lastly, the percent undiagnosed by transmission category, a person who said they were HIV-negative or not tested on the survey and their test result was positive. Along with each concept, she listed statistics. A final concept is incidence -- the number of new HIV infections. About 53% of all new infections are among MSM, 31% infected through heterosexual contact, 12% injection drug use, and 4% among MSM who are also IDUs. She then listed new infection statistics by age group.

Transfusion-associated transmissions of HIV

Dr. Bernard Branson, Associate Director for Laboratory Diagnostics, CDC and Division of HIV/AIDS Prevention was the next presenter. The outline of his presentation was to first describe a few definitions of terms, followed by a description of the transfusion-associated cases of HIV and investigations of suspected cases. He pointed out that the CDC does become involved in transfusion- associated cases of Human Immunodeficiency Virus, but most of the investigations of suspected cases occur from the blood industry. Following, Dr. Branson gave background and statistics on several cases, along with the results. He discussed the observed HIV prevalence and estimated residual risk in the donor population and also the cost-effectiveness of screening technologies. In addition to HIV figures, he spoke on hepatitis B, C, HBV and HCV transmissions. Hepatitis B continues to occur in men who have sex with men. Hepatitis C may be occurring in MSM who are HIV infected and who are having unprotected sex with other HIV infected men, however the impact of this trend on the blood supply is moot. Given the imperfections to detect and find hepatitis B and C infections, they have not been able to detect any from transfused blood. The risk of current transmission of hepatitis B and C through transfused blood is extremely low. This can be attributed to declining incidence, deferral of high-risk donors, use of NAT and serologic tests.

Behaviors and Other Risk Factors Associated with Viral Hepatitis B and C

Dr. Holmberg introduced the next presenter, Dr. John Douglas, Chief Medical Officer, National Center for HIV, Viral Hepatitis, STD, and TB Prevention. He began by way of overview to say that there's a lot not known about STDs in the U.S. There are several characteristics in STDs and number one is that STDs are largely associated with age and our youth comprise the majority. Secondly, is racial and ethnic minority status; and finally, men who have sex with men. Dr. Douglas went into great detail about each STD and statistics for the various groups mentioned. He also spoke about the current testing strategies. The most consistent risk factors are STD incidence in prevalence and nationally representative samples are age and race ethnicity. MSM behavior accounts for some, but not all sexually transmitted diseases.

Status of Current Transfusion Transmitted Disease Testing: Sensitivity, Cost, Window Period and Residual Risk

The next speaker was Dr. Michael Busch, Director of the Blood Systems Research Institute and Research Scientific Affairs Blood System. He first gave context to the historical approach of risk assessment. Then spoke about the volatile dynamics and the infectivity of the window phase and addressed the recent data from The Red Cross on prevalence and incidence. He applauded The Red Cross for the work they have done. Dr. Busch ran through the NAT yield rates. He noted it was probably the best insight into the window phase donations and the summary of the current risk over time for the three major viruses. He went through slides on national and international data for HIV infections. Next, he discussed the CDC and FDA's efforts to understand the potentially emerging infectious diseases and consider whether the historical MSM was pertinent. Lastly, Dr. Busch gave information on the cost of testing. He referenced the cost of donor screening in Canada and in the U.S. on testing for various pathogens.

Formal Risk Assessment in the U.S.

Dr. Andrew Dayton, Medical Officer Researcher at the FDA, presented the results from assessed risk of mostly HIV risk that would be associated with various changes in the MSM deferral policy. There are basically three ways that units can get out of this blood bank quarantine and into circulation. One, if there are window period units and they sneak through. Quarantine release errors, no test will do you any good if there is an error. The only detection against quarantine release errors is deferral. The third way things can get out is by false negative testing. He showed the model of what happens with things that are in quarantine and how bad things get out, considering change in risk and change in the size of the donor pool with specific characteristics being modeled. He moved on to discuss window periods. When looking at changes in deferral policy, one year or more, you're not going to see any change in the numbers of window period units that you're letting in. The window period term drops out to zero. Dr. Dayton discussed caveats at the conceptual level, not just the statistical level. HIV doesn't disappear; the prevalence is not going to go down unless people are dying. It has been suggested that a relaxed deferral or shorter deferrals could improve the appearance of fairness in the system and result in better compliance. There is a small Swedish study which suggested that might be the case. In summary, the bottom line is that the risks that are calculated for HIV are small, but potentially significant.

Current Review of MSM Policy in Canada

Dr. Peter Ganz, Director of the Centre for Blood and Tissue Evaluation, Biologics and Genetic Therapies Directorate Health Canada, was introduced by Dr. Holmberg. First off, Dr. Ganz stated they have very good blood operators in Canada who are highly compliant with the regulations. There has been an evolution in the way they do donor screening in the scope of the kind of activities they carry out Canada has geographic behavioral and medical-type deferrals which he

thinks are quite important because for many of these kinds of interventions, they're generally very inexpensive as opposed to implementing tests. For risk managing certain kinds of infectious diseases for which they do not have tests, they may be able to reduce risk through donor screening measures. Canada has a primary mandate similar to FDA's of ensuring that blood products that are available are as safe. Dr. Ganz recognizes that no medicinal product -- be it a blood product or another kind of medicinal is ever going to be 100% safe. Canada's policies for donated blood include: donor screenings are not meant to discriminate against any individual or group. The MSM question seeks to identify prospective donors who have taken part in activities that have been through surveillance activities or studies placing participants in higher incidence of blood borne infections. They try to screen out groups of higher risk, but sometimes that happens at the expense of those that carry less risk. Countries where MSM donor deferral has been relaxed, there are no long term studies to his knowledge or data collected to whether the incidence of HIV transmission from blood may have changed to support the relaxation of criteria. Dr. Ganz noted several issues they would look at before changing the deferral period for MSM in Canada. First, requirements are reviewed as new science and new data becomes available. Any change would need to be supported by scientific evidence. Some of the factors that they would look at would be published literature, surveillance vigilance data, model data, and global experience. What are Canada's current and future strategies for addressing infectious disease risks? Donor deferral algorithms are very important in excluding individuals that develop tests for a known risk for transfusion and surveillance measures. Health Canada feels that donor screening is the cornerstone of safe blood systems.

Current Review of Donor Deferral Rules Including MSM by the Transfusion Committee of the European Directorate for the Quality of Medicines (EDQM), Council of Europe (CoE)

Dr. Rut Norda, from the UPPSALA, University Hospital and she's the Coordinator of National Statistics British Society for Transfusion Medicine. She first gave background on the Council of Europe and the ways they try to cooperate with regulatory bodies in Europe. There has been a resolution by the Council of Europe on donor responsibility and on limitation to donation of blood and blood components. The resolution has been drafted by the committee members as a response to the discussions of whose rights comes first -- the donors or the recipients. Blood donor screening in Sweden is collected by the Swedish Transfusion Medicine Society, which aids the Swedish national institute for infectious disease control. Dr. Norda noted the majority of not previously tested donors are not allowed to donate blood on first visit. There was a discussion of deferral of the model to none, six months, or permanent. She proceeded to give statistics on modeling in Sweden before ending her presentation.

Current Status of Computerized Inventory Management in Blood Collection Establishments (National, Community-based and Hospital-based)

The next speaker, Theresa Wiegmann, AABB Director of Public Policy, was introduced. Ms. Wiegmann first gave background information on AABB, including the status of being a non-profit. AABB's standards and accreditation programs are designed to ensure that a blood component is released for further distribution or transfusion only when a number of associated manufacturing records have been reviewed at each critical step along the process. She went into each step in further detail and the criteria each collection center and hospital must conform to. Ms. Wiegmann stated virtually every blood center in the United States, all but one small center in Kentucky, is currently an AABB member and accredited. Several hospital statistics were given on those accredited and those not. The information given was to show what blood collection facilities needed to conform to, to prevent the inappropriate release of units and avoid the quarantine release errors.

Quarantine Release Errors

Ms. Sharon O'Callaghan from the FDA, Program Surveillance Branch, was the next speaker. She first discussed the biological product deviation reporting system. It is a mandatory requirement, but passive meaning they have to wait for the firms to submit the reports. The reporting requirement is limited to events associated with distributed products. Licensed manufacturer means they can distribute product in interstate commerce. Unlicensed registered blood establishments are required to report. Transfusion services are also required to report. The requirement for reporting states is that a facility must report any event associated blood components that deviates from current standards or specifications that may affect the safety or potency, or represents an unexpected or unforeseeable event that may affect the safety or potency and occurs in their facility or facility under contract with them. Ms. O'Callaghan then provided the summary of the BPD reports and calculated quarantine release error rates to the committee. She stated they include antibody, antigen, confirmatory, supplemental and nucleic acid testing. They looked at the reports by type of manufacturer, separating it out to blood and plasma. In addition, they looked at the reports in which a positive unit was inadvertently released. As part of the reporting mechanism for BPD reports, they identified deviation codes to trend the reports easier. They will breakdown the events by type of manufacturing operation so they have the donor suitability and QC distribution. Ms. O'Callaghan brought up statistics in regards to plasma establishments and commented there are very few of failure to quarantine issues. When compared, there was no significant difference in the quarantine release error rate comparing these the time periods 2003 to 2005 and 2006 to 2008, but she did note that there was an 18% drop in inventory repeat reactivities for any agent.

Reliability of Donor Questionnaires to Address High Risk Sexual Behavior

Historical Data on Donor Question Development and Validation

The first speaker on this topic was Dr. Alan Williams from the FDA Office of Blood Research and Review. Dr. Williams first listed the five layers of safety that help maximize safety of the U.S. blood supply. One is how to determine donor eligibility by an interview questionnaire

process. Two, minimize donor loss due to inappropriate deferral. Three, if you never collect an infectious unit of blood, you never potentially expose staff to infectious material. Four, is gathering post-donation information. Five, a donor history task force was put together. The National Center for Health Statistics was contracted to do a cognitive assessment of the newly streamlined questionnaire. Dr. Williams noted it was done through one on one interviews with staff and individuals who had been recruited as the equivalent of potential donors. The validation of the questionnaire is very, very difficult, in part because of the inability to establish a gold standard with which to prepare a questionnaire response definition. Dr. Williams went on to document for the record and the committee several questions in the Donor History Questionnaire. The outcome of the efforts by the task force and review by FDA was an acceptance of a specific version of this questionnaire. He stated that evaluating the performance of the questionnaire is difficult for a number of reasons. One has to do with the difficulty in providing validity measures. The second has to do with the fact that this questionnaire is being administered in a regulated environment. One can look at prevalence of incidence measures among the donors collected by a blood center, rates of deferral and first-time donors. We ran through some challenges related to the donor questionnaire process. One was regarding heterosexual risk. Another is when a donor is found to be positive; they usually appear for counseling and notification. Dr. Williams had a couple slides that related to behavioral science challenges. They include: the blood donor questionnaire, educational barriers, cultural differences, plus some people don't like to sit down and read a long questionnaire and the redundancy for repeat donors. Finally the doctor noted, human behavior underlies many aspects of the blood donation process.

Risk Behavior, Recall and Accuracy

Dr. Beryl Koblin from the New York Blood Center was the next presenter. She focused on how one may be looking at the idea of measuring risk behaviors and ways that the committee might be able to improve information that is given on the questionnaires. She started with self-reported sexual behaviors on HIV infection and moved onto looking at factors that can influence sexual behaviors and what are different approaches that could be taken. Are self-reported behaviors among men who have sex with men a good measure of HIV risk? Dr. Koblin went through several studies done in other countries to see if self-reported behaviors were a good measure. She went on to say the studies that have been done in the African countries have not worked as well as they have here in the United States. Next she spoke on factors that influence sexual behaviors and stated reporting varies by gender, by ethnicity, by age. It also depends on what we set up as the recall period and the use of and thinking about that recall period, the type of question and the level of detail. The more detail can provide an environment where the behaviors that are asked about are more normative. Dr. Koblin moved to the mode of administration, ASCI: it can reduce burden on respondents, eases data management, reduces missing data, helps if there's literacy issues, has demonstrated acceptability in many populations and it does increase reporting of sensitive behavior. In summary she stated, biomarkers for validation of sexual behaviors is clearly needed.

It was noted that it might be better to have a little bit more explicit type of questions that would draw out more than just a yes-no response. Dr. Koblin answered yes. Dr. Epstein wondered if it was possible to get the same level of discrimination of risk among MSM by asking gender neutral questions. Dr. Holmberg made a point of clarification and injected a question might be to the extent of, have you had anal sex. Dr. Koblin did not think that question was a good way to

go, but offered other advice. Ask people if you've had sex as a gateway question. Then, have you had sex with only men? Have you had sex with only women? Have you had sex with both?

Closing Comments: Dr. Holmberg told the committee they would try to have the presentations that they could not duplicate for today's meeting tomorrow morning. There was a request to start the morning meeting at 8:00 a.m., which was agreed upon by the committee. He asked the committee to go over the discussion points for tomorrow's meeting: societal, scientific, and economic items to consider in making policy changes. Dr. Holmberg then ran through some questions to consider. Dr. Kouides pointed out it would be helpful to have a paper trail to review the material supplied to the committee from the various groups and organizations.

Adjournment

Dr. Holmberg adjourned the 39th meeting of the U.S. Department Of Health And Human Services Advisory Committee For Blood Safety And Availability

Friday, June 11, 2010

The 39th meeting of the Advisory Committee on Blood Safety and Availability convened at The Universities at Shady Grove, 9630 Gudelsky Drive, Rockville, Maryland. Jerry A. Holmberg, PhD, Executive Secretary, Designated Federal Official, Chair, was presiding.

Opening Remarks: Dr. Holmberg welcomed committee members and opened the second day of the 38th Advisory Committee on Blood Safety and Availability.

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

Roll Call: It is noted a quorum is present.

Hemovigilance and Data Sets

Potential Data Sources for Identification of Low-risk MSM Subsets

Dr. Holmberg introduced Robert Reinhard. It was noted Mr. Reinhard does not come from any affiliation, government agency or any organization. Robert Reinhard stated he would not be advocating for any particular criterion, but only describe low-risk screening using a few definitions that have been successfully achieved. He reviewed some of the topics from yesterday's discussions on low-risk screening and commented that his examples come from work he has done with NIH Vaccine Trial Networks and Phase 1 HIV Preventative Vaccine Trials conducted in the United States since 1988. He offers real-time comparison with the broad general population found to be low-risk for infectious agents and pathogens, with the eligibility requirement being no HIV exposure. Healthy adults are selected by means of behavioral history questionnaires and confirmatory testing. Mr. Reinhard went on to list the major sources of information for Phase 1 Screening and Statistics, such as over 1,000 participants out of 2600 enrolled on U.S. Phase 1 Trials from 1988 through 2002 were homosexual or bisexual. Another study cited 40% of men were identified as MSM. In a question posed, what is considered low-risk behavior, Robert Reinhard showed a composite indicator of what was considered low-risk. It allows for screening questions that can be asked for MSM and other participants. Following up on yesterday's conversation to improve the screening questions and methods for all donors he listed some limitations, referenced Dr. Koblin's answer to Dr. Corash from yesterday's session and mentioned it will require a lot of stakeholder involvement and community engagement and the need to expand the donor pool population.

Risk Factor Interviews and Infectious Marker Surveillance

Dr. Holmberg introduced the next speaker, Dr. Brian Custer, Associate Investigator at The Blood Systems Research Institute. Dr. Custer spoke about a new study initiative, transfusion transmitted retrovirus and hepatitis rates and risk factors; improving the safety of the U.S. blood supply through hemovigilance. The project will be funded through The National Heart, Lung, and Blood Institute and they are in contract negotiations with NHLBI. He acknowledged The Red Cross and other participants in the project. The idea is to bring those three organizations together to collect

risk factor information and develop a research partnership. Dr. Custer indicated the three originations stated represent a sampling of about 60% of the blood collected in the United States. The goal is to do surveillance for a year on infectious markers to get a representative sample for the entire country. He went through slides listing the collection data for each organization. The predominate HCV risk factor is intravenous drug use, occupational exposure and the controversial and unclear risk factor of sex with an IDU or sexual transmission. Hepatitis B risk factors for males and females are multiple sexual partners, MSM, intravenous drug use and family history or being from an endemic area. HTLV risk factors include: being from an endemic area, more than seven sexual partners, intravenous drug use, or sex with an IDU. Dr. Custer noted the work done by ARC, which showed a slight decrease to consistent prevalence of HIV in first-time donors. In contrast, the data from Blood Systems showed an increase in HIV prevalence. He stated these could be regional differences. Moving through more slides, Hepatitis C prevalence in repeat donors from ARC and Blood Systems showed a downward sloping trend. HCV incidence showed a slight uptick. Hepatitis B shows a potential age cohort issues between persons 30 to 39. Dr. Custer proceeded to say if funding was secured the four main areas of focus would be to define consensus infectious disease; testing classification algorithms for HIV, HCV, HBV and HTLV; to do surveillance, determine current relative distribution of behavioral risk factors and other exposures associated with prevalent and incident HIV, Hepatitis C, Hepatitis B and HTLV infections to determine national representative infectious disease marker prevalence and incidence for the same infections overall and by demographic characteristics of donors; and finally combining the entire database and risk factors to look at geographic distribution of risk factors. Aim One, Blood Systems Laboratory now known as Creative Testing Solutions is moving to the combination of testing. The idea is to bring the three organizations together to interpret the results in a similar way. Mr. Custer proceeded to the risk factor study's goal, which is to identify and interview as many HIV confirmed positive and HTLV confirmed positive donors as possible during the study period and compare the risk factors reported. The results will be compared to false reactive donors for the same virus. The control group or comparison group will not include indeterminates. Donors who donated are tested according to the standard operating procedures at each organization. They are classified as being repeat reactive and confirmed positive or false reactive. HIV-positive with multiple infections will be counseled and interviewed in person and for other factors the interview will be done via telephone. A draft of the Blood Systems document was shown, which is similar but not exact to the other two organizations. Dr. Custer explained the interview process to the group and the questions asked to the donor. The goal of the study is to interview 362 HIV-positives though the sample of 500 HCV-positives and 500 HTLV-positives, doubling the number for false reactives and controls. Once complete a distribution of risk behaviors and stratified distributions for each virus will be done based on demographic characteristics. He stated summary data published for W.H.O. was very important on marker rates and the denominators. The final piece of the project will be an integrated disease marker database that will take place at the ARC Holland Lab to look at risk factors in incident versus prevalent infections for donors. Mr. Custer finished by summarizing the process a final time.

Societal Consideration of MSM Deferral Policy - Medical Ethics Consideration

Dr. Holmberg introduced the first speaker, Ms. Lori Knowles, Health Consultant from the University of Alberta Consultant, Biotechnology Policy, Law and Ethics. He mentioned that this

study is to be funded by the NHLBI, but hemovigilance does not have ongoing funding. After a few opening remarks, Ms. Knowles ran through her agenda which included framing the issues using ethics, making comments about discrimination and creating differences and distinctions between groups, populations, and lifetime deferrals. Then commented about how to think about costs, how ethics informs policy, how historical and cultural context matters in creating, changing, and analyzing policy and posed questions to be asked going forward. Focusing on the framing issue, there are several different ethical points of view or philosophies that inform our understandings of how to frame the values at stake. Framing includes rights-based articulation, duty-based, and utilitarian or consequentialist types of articulation. To create a fair and just society, distinctions can be made but they need to serve a meaningful purpose. Ms. Knowles cited the Canadian Blood Services vs. Freeman case to make a point that the Canadian blood donations policy is in flux. Does the MSM deferral as it is currently drafted send messages of discrimination, stigmatism, prejudice, or stereotyping? We need to be extremely aware of and try to understand what the assumptions are and the value judgments underneath that assumption. There is a population that is in some way potentially an incubator for future unknown diseases. The costs

reported include: lost lives, lost units of blood, loss of donors, loss of confidence in the system and loss of cooperation from the community and the compliance that comes with it. Ms. Knowles made a few points about ethics, science and policy. The rule of ethics should and does inform policy. How science is used is the rule for science and also a value-laden judgment. Rights are such that inequalities are minimized. There is transparency of assumption, and there is a responsibility. Historical and cultural context matter impacts policy. The last slide listed several questions that should be asked, from Ms. Knowles' point of view, moving forward.

Gay Men's Health Crisis

Nathan Schaefer, Director of Public Policy, and Dr. Sean Cahill, Managing Director of Public Policy Research and Community Health of Gay Men's Health Crisis, were the next speakers to talk about the perception of the current MSM Deferral Policy. First, Nathan acknowledged that gay and bisexual men are disproportionately impacted by HIV, but not all gay men are HIV-positive. They were not advocating that all gay men should be able to donate blood, but believe that a subset of low-risk gay and bisexual men could become eligible blood donors. Some fundamental concerns are since the time the current policy was implemented there have been significant advancements in HIV screening and testing technologies, and also the inconsistencies in blood donation guidelines. He reiterated a desire for a comprehensive review of current policy and a comprehensive assessment of potential alternatives. Dr. Sean Cahill began by stating a man having sex with another man is not in and of itself a high-risk behavior, but unprotected anal sex is. Even though gay men are more vulnerable to HIV, most gay men practice safer sex. Safer sex rates are about twice the rate of the heterosexual population. He then gave statistics on gay men and HIV. He worries deferring MSM donors provides a false sense of security to heterosexual donors and creates a false perception of low risk for heterosexuals, not only for HIV but for other STDs. This is a missed opportunity to promote public health and safer sex practices for everybody. Because of the concern that potential lifetime donors are alienated by this policy that they perceive to be discriminatory, there have been a number of protests at campus blood drives. Finally,

this poses problems and issues of coming out. Dr. Cahill reiterated the advances in testing, but the same total lifetime ban on all MSM is still in place. He proceeded to list viable alternative policies: a five-year deferral for MSM and a one-year deferral, and cited and explain several articles and studies that show the benefits of lifting the life-time ban. Nathan Schaefer spoke on an alternative policy, behavioral-base deferral, or objective screening. All donors would be asked about high-risk activity of all genders, irrespective of sexual orientation. He noted a couple examples of countries with this policy in place. Some final comments: consider screening all donors for high-risk behavior, encourage you to thoroughly review the value-based donors, to expand existing research to support change and to review the piece Dr. Koblin mentioned yesterday from The Family Growth Data from 2002 and investigate that technology. They would also like to see if a pilot program could try out and test the alternate policy. In finishing, some comments were made on the racial disparities data presented in yesterday's meeting. The first question came from Dr. Epstein asking Sean and Nathan to clarify the data cited from Italy concerning the number of transmissions. Dr. Norda announced the testing in Italy for the donors was introduced in 2005 and that could be a significant factor.

Consumers' Consideration

Mark Skinner representing the American Plasma User Coalition stepped to the microphone. He started with this issue isn't just an issue about MSM or the gay community, but an issue about high-risk behaviors. HIV dramatically impacted both of our communities in a very devastating way. A copy of a statement was distributed, a very important coming together and recognition that we do want a scientific-based system. Mr. Skinner listed four potential options for the board: the status quo, a completely lift the deferral, research and revision. He listed five committee questions that have been published in The Federal Register and took the committee through his coalition's answers in detail. What are the most important societal, scientific, economic factors to consider in making a policy change? The most important principle to them is the precautionary principle. Is the currently available scientific information, including risk assessments, sufficient to support a policy change at this time? No. What studies if any are needed before implementing a policy change? Mr. Skinner listed five areas of study. What Monday morning tools or surveillance activities would need to be in place before implementing a policy change? The answer is hemovigilance and biovigilance. For the approval of pathogen reduction technologies, his team would suggest that this committee convene a meeting to look at what's available elsewhere in the world. Donor education and marketing comes down to what happens with the end donor.

Open Public Comment

Corey Dubin, President of the Committee of Ten Thousand. The committee is committed to working with GMHC. His first comment was a follow-up from yesterday's discussion on Health Canada. Their position is to not approve changes in blood operations which will increase risk, but to review and approve changes which will increase safety or at least maintain the current level of safety. The nation's blood and blood products to remain free from disease is a question of survival, not politics. He believes for HIV, HBV and HCV nucleic acid testing is effective, but it can only be effective in a quality GMP environment. The issue he wanted to focus on was that the end users bear the sole responsibility when the system fails and thinks it's time to put

financial resources into developing a no-fault compensation system that is a more humane and effective way to deal with failure. Ms. Finley asked what is the average cost of blood injuries are. Cory Dubin reported his total cost of care including HIV and when his immune system crashed was close to \$11 million.

Richard Vogel from the Hemophilia Association of New Jersey was the next speaker introduced. He spoke of several incidences in his life, such as having severe hemophilia A, HIV and hepatitis C, the latter two from blood products. Mr. Vogel believes it is not the time to consider revising the deferral program because it is the end users who take the brunt of the decisions.

James Sykes, Director of Global Programs, Policy and Advocacy at the AIDS Institute. He appreciates the committee reviewing the FDA's policy of deferring all men who have sex with men as far back as 1977 from ever donating blood and stated the advancement in technology. Mr. Sykes pointed out the decisions should not be made based on one's sexual orientation.

Andrea Weddle, Executive Director of The HIV Medicine Association. Her association strongly supports basing the decision on science rather than politics and urges the FDA to revise the blood donor deferral criteria to address all potential donors to exclude themselves if they have tested positive for HIV or within the previous six months engaged in unprotected sex with a partner of unknown HIV status. Ms. Weddle also urges the committee to promote evidence-based policies and strengthen the security of the blood supply by modifying the blood donor deferral criteria-based and behavior-based on HIV risk behavior rather than the blanket exclusions of population groups.

Chris Collins, Vice President and Director of Public Policy, amfAR, thinks the current policy is outdated and may facilitate stigma against the millions of gay and bisexual men. The current FDA blood donation policy treats men who have sex with men differently than other population groups that are at elevated risk. His association urges the committee to seriously consider implementing a reduced deferral period.

Lee Storrow, a senior at the University of North Carolina at Chapel Hill, gave background information on his years of experience donating blood as a gay man. He did this until he checked the box on the donor form that made him no longer eligible. He thinks this policy does discriminate toward gay citizens.

Dr. Charlene Galareau, faculty at Wellesley College, stated she's not representing the college. She finds this policy to be unfairly discriminatory and urges the FDA reconsideration of it in its revision. She cited an article she wrote while at Boston University and six factors that lead to this unfair discriminatory effect.

Dr. Ruth Jacobs, an infectious disease specialist, voiced her concerns with changing the deferral policy. If you lift your ban and say it's a one year, and you haven't defined sex with men, somebody may think he is monogamous but he's not really monogamous. His partner is doing things and he just doesn't know it. In ending she quoted a patient of hers, it's a privilege to donate blood, but it's a right to have safe blood.

Cliff Kincaid, President of America's Survival Incorporated -- a public policy organization. He presented testimony by Dale O'Leary, a writer who has followed the AIDS epidemic. Mr. Kincaid posed those lobbying are focused entirely on improved tests for HIV and do not mention all the other infectious diseases epidemics. He acknowledges the current policy is discriminatory, but deferral criterias are discriminatory. Although testing for known pathogens have improved, current methods are not perfect and an increase in donations would increase the risk of infected blood.

William McColl, Political Director at AIDS Action Council based in Washington. His council believes changing the guidelines would bring greater openness to the system, create better donor education and ultimately result in a safer donation system. Stating the current policy banning men who have sex with men is discriminatory and stigmatizing and fails to distinguish low-risk from high-risk males.

Theresa Wiegmann from the AABB, will be speaking on behalf of AABB, America's Blood Bank Centers and The American Red Cross. The three organizations presented a joint statement to the FDA stating the current lifetime deferral for MSM is medically and scientifically unwarranted and recommend that the deferral criteria be modified and made comparable to other groups with increased risk of transfusion transmitted infections. She noted improved testing and zeroing in on high-risk behaviors.

Michael Halperin wanted to share his perspective as a gay man in his early 30s. He explained his desire to give blood from an early age and could do so until he had protected sex with a man. He asks the committee to fight the insinuation that all gay blood is tainted blood.

Peter Sprigg from The Family Research Council in Washington urged the committee to maintain the current policy. Any change in this policy should occur only if it can be demonstrated that it will improve both the availability and the safety of the nation's blood supply and no such evidence is available. In finishing, Mr. Sprigg stated only the scientific evidence matters, which indicates that the current policy should remain in place.

Jay Rhodes Perry. Mr. Perry was absent, but did leave a statement to be read. Dr. Holmberg read the statement from Senator John Kerry into the record. Senator Kerry supports a revision of the current deferral policy.

Analysis of Policy Options by the PHS Working Group

Dr. Holmberg expressed that the government has tried to stay very neutral in opinions and comments trying to solicit comments from the committee members. Now is the committee's opportunity to voice to the government concerns and comments. Dr. Rick Davey, Co-Chair of The Public Health Service MSM working group, was introduced. The entire group has spent the last months really going through the issues, the science, and also the various options that potentially could be considered. Dr. Davey will be presenting the policy options for the committee's consideration. He wanted to commend the members of the task force for their input and thought it was very reflective of the broad range of thinking within the department. Dr. Davey then listed the options to the board along with benefits and limitations.

Option 1, would be no change to the current policy. Option 2, is a ten-year deferral following last MSM exposure. Option 3, would be a five-year deferral following the last MSM deferral. Option 4, is a one- year deferral following the last MSM exposure. Option 5, would be no specific deferral, but have gender-neutral questions based on specific high-risk activities. He reiterated the options to the committee were not presented in any kind of prescriptive or restrictive way.

Dr. Holmberg called for a vote in favor of having the question. The ayes had it and the question was given: should the current indefinite deferral for men who have had sex with another man even one time since 1977 be changed at the present time? Dr. Holmberg called for a vote to change the current deferral. The nays had it as far as any change.

The next question: what studies are needed to establish a sound basis for change of policy? Dr. Holmberg wanted to show support to the question and asked Ms. Birkofer to read ten points of recommendation into the record. Dr. Pierce recommends the agency take these into account as they develop a path forward and a plan.

Moving forward, Dr. Holmberg asked the committee to discuss a road map. The following was given to develop and validate candidate alternative policies and recommend research in the following areas: Number 1, validate modifications to the donor questionnaire that would better differentiate low versus high-risk MSM and heterosexuals. Number 2, establish ongoing hemovigilance for TTID blood markers and blood donors linked to analysis of demographic behavioral and other risk factors. 2a, obtain a baseline on prevalence and incidence of TTIDs to be characterized risk and different donor subgroups.2b, such as those younger in age. 3, determine the feasibility of donor pre-testing to limit risk while characterizing donors who might be recruited under modified eligibility criteria. Number 4, investigate the impact of revised donor criteria on the global availability of plasma products. The committee discussed several revisions and additions to the previous road map and came up with the following wording: Additionally, the committee recommends the following actions. Number 1, implement the January 2008 ACBSA recommendation of Pathogen Reduction Technologies for all transfusable blood components. Number 2, create a more robust education program focusing on high-risk behaviors that is all-inclusive of all donor groups, emphasizing the link between safe donation and recipient health. Number 3, the department should take action to investigate and reduce the risk of quarantine release errors from blood collection establishments. Number 4, recognizing the relationship between acceptance of risk of transfusion and protection from harms. Further consideration should be given to mechanisms for compensation for blood injuries consistent with the recommendations of the IOM and the congress.

Dr. Holmberg called for a vote. The ayes had it and it was unanimously passed.

Adjournment

Dr. Holmberg adjourned the 38th meeting of the Advisory Committee on Blood Safety and Availability at 4:18 p.m.