Public Workshop: Identification and Characterization of Infectious Disease Risks of Human Cells, Tissues, and Cellular and Tissue-Based Products

February 8-9, 2017

Wiley Auditorium, Harvey H. Wiley Federal Building

5001 Campus Dr., College Park, MD 20740

Draft Agenda – Day 1	
Introduction	
8:30 am – 8:40 am	**Welcome Address** Wilson Bryan, M.D. (Food and Drug Administration)
Session I: Estimating Magnitude of Emerging Infectious Diseases **Moderator: Michael Strong, Ph.D. (StrongSolutions)**	
8:40 am – 9:00 am	**Emerging infectious diseases in the U.S.** Bob Bollinger, M.D. (Johns Hopkins University)
9:00 am – 9:15 am	**Predicting the potential impact of an emerging infectious disease on public health** Mark Roberts, M.D. (University of Pittsburgh)
9:15 am – 9:30 am	**Estimating disease incidence/prevalence in general and donor populations** Brad Biggerstaff, Ph.D. (Centers for Disease Control and Prevention)
9:30 am – 9:45 am	**Estimating disease incidence/prevalence in the HCT/P donor population** Don Brambilla, Ph.D. (RTI International)
9:45 am – 9:55 am	**Q&A**
9:55 am – 10:40 am	**Panel Discussion** **Panel Members:** Bob Bollinger, M.D. (Johns Hopkins University) Mark Roberts, M.D. (University of Pittsburgh) Brad Biggerstaff, Ph.D. (Centers for Disease Control and Prevention) Don Brambilla, Ph.D. (RTI International)
10:40 am – 10:50 am	**Break**
Session II: Potential for Donor-Derived Infectious Disease Transmission by HCT/Ps **Moderator: Matt Kuehnert, M.D. (Centers for Disease Control and Prevention)**	
10:50 am – 11:05 am	**History of infectious disease transmissions by human cells and tissues** Matt Kuehnert, M.D. (Centers for Disease Control and Prevention)

11:05 am – 11:20 am	**Infectious disease transmissions by conventional tissues** Ted Eastlund, M.D. (University of New Mexico School of Medicine)
11:20 am – 11:35 am	**Infectious disease transmissions by ocular tissues** Marian Macsai, M.D. (NorthShore University HealthSystem)
11:35 am – 11:50 am	**Infectious disease transmissions by HPCs** John Miller, M.D., Ph.D. (National Marrow Donor Program)
11:50 am – 12:05 pm	**Infectious disease transmission by reproductive cells and tissues** Deborah Anderson, Ph.D. (Boston University)
12:05 pm – 12:20 pm	**Relevant communicable disease agents and diseases** Brychan Clark, M.D. (Food and Drug Administration)
12:20 pm – 12:35 pm	**Q&A**
12:35 pm – 1:35 pm	**Lunch**
1:35 pm – 2:20 pm	**Panel Discussion** **<u>Panel Members:</u>** Matt Kuehnert, M.D. (Centers for Disease Control and Prevention) Ted Eastlund, M.D. (University of New Mexico School of Medicine) Marian Macsai, M.D. (NorthShore University HealthSystem) John Miller, M.D., Ph.D. (National Marrow Donor Program) Deborah Anderson, Ph.D. (Boston University) Brychan Clark, M.D. (Food and Drug Administration)
Session III: Challenges of Traditional Screening and Testing Approaches for Donors of HCT/Ps **Moderator: Jay Fishman, M.D. (Massachusetts General Hospital/Harvard Medical School)**	
2:20 pm – 2:35 pm	**Current approaches for HCT/P donor screening and testing** Michelle McClure, Ph.D. (Food and Drug Administration)
2:35 pm – 2:55 pm	**Screening and testing of HCT/P donors** David Gocke, M.D. (Musculoskeletal Transplant Foundation) Jennifer Li, M.D. (University of California Davis Eye Center)
2:55 pm – 3:10 pm	**Test performance when using post-mortem blood** Harry Prince, Ph.D. (VRL-Eurofins)
3:10 pm – 3:25 pm	**Pathogen persistence and infectivity in cells and tissues: Zika virus** Graham Simmons, Ph.D. (Blood Systems Research Institute)
3:25 pm – 3:35 pm	**Q&A**
3:35 pm – 3:45 pm	**Break**

3:45 pm – 4:30 pm	**Panel Discussion** **<u>Panel Members:</u>** Michelle McClure, Ph.D. (Food and Drug Administration) David Gocke, M.D. (Musculoskeletal Transplant Foundation) Jennifer Li, M.D. (University of California Davis Eye Center) Harry Prince, Ph.D. (VRL-Eurofins) Graham Simmons, Ph.D. (Blood Systems Research Institute)
4:30 pm	**Adjourn Day 1**
Draft Agenda – Day 2	
8:30 am – 8:45 am	**Recap of Day 1** Scott Brubaker (Food and Drug Administration)
Session IV: Characterization of Infectious Disease Risk to HCT/P Recipients Moderator: Richard Forshee, Ph.D. (Food and Drug Administration)	
8:45 am – 9:05 am	**Benefits, Risks, and Alternatives** Richard Forshee, Ph.D. (Food and Drug Administration)
9:05 am – 10:05 am	**HCT/P Recipients and Exposures** William Tomford, M.D. (Massachusetts General Hospital) Richard Jonas, M.D. (Children's National Medical Center) Richard Kagan, M.D. (R.J. Kagan Consulting) Jennifer Li, M.D. (University of California Davis Eye Center) Jaime Shamonki, M.D. (California Cryobank) David McKenna, M.D. (University of Minnesota)
10:05 am – 10:20 am	**Applying Results of a Benefit-Risk Analysis** George Gray, Ph.D. (George Washington University Milken Institute School of Public Health)
10:20 am – 10:35 am	**Q&A**
10:35 am – 10:50 am	**Break**
10:50 am – 12:30 pm	**Panel Discussion** **<u>Panel Members:</u>** Richard Forshee, Ph.D. (Food and Drug Administration) William Tomford, M.D. (Massachusetts General Hospital) Richard Jonas, M.D. (Children's National Medical Center) Richard Kagan, M.D. (R.J. Kagan Consulting)

	Jennifer Li, M.D. (University of California Davis Eye Center) Jaime Shamonki, M.D. (California Cryobank) David McKenna, M.D. (University of Minnesota) George Gray, Ph.D. (George Washington University Milken Institute School of Public Health) Michael Strong, Ph.D. (StrongSolutions) Matt Kuehnert, M.D. (Centers for Disease Control and Prevention) Jay Fishman, M.D. (Massachusetts General Hospital/ Harvard Medical School)
12:30 pm	**Adjourn Day 2**