

CDR Jennifer Doe
PHS Number
Medical Officer
FDA Center for Biologics Evaluation and Research
Office of Cellular, Tissue, and Gene Therapies
Division of Human Tissues
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EDUCATION AND POST-GRADUATE TRAINING

1998-2000	Internal Medicine Residency, National Naval Medical Center, Bethesda, MD
1997-1998	Internal Medicine Internship, Naval Medical Center Portsmouth, Portsmouth, VA
1993-1997	Medical Doctorate, Uniformed Services University of the Health Sciences, Bethesda, MD
1990-1993	Bachelor of Science Environmental Health, East Tennessee State University, Johnson City, TN
1988-1990	Associate of Science Environmental Health, Roane State Community College, Oak Ridge, TN

PROFESSIONAL LICENSURE AND CERTIFICATIONS

2010	Basic Life Support
2000	American Board of Internal Medicine Board Certification
2010	American Board of Internal Medicine Maintenance of Certification
1999	Washington, DC License Number MD31800
1999	National Board of Medical Examiners (Parts 1, 2, 3)

SECURITY CLEARANCE

6/2004-6/2014	Secret Security Clearance
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USPHS ASSIGNMENTS

3/2010-present Chief, XX Branch, Division of XX (DHT), Office of Cellular, Tissue and Gene Therapies (OCTGT), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA)

Major Duties:

- Lead and coordinate OCTGT/CBER policy initiatives related to donor screening and testing for cell and tissue donors
- Immediate supervisor of all staff within DHT
- Supervisor with sign-off authority for all Division work related to regulatory review of infectious disease tests used to test donors of cells and tissues
- Subject matter expert, leader and nationally recognized authority on issues related to human cell and tissue donor screening and testing, regulatory review of donor screening test kits used to test deceased tissue donors; representing OCTGT within the Agency, to other government agencies and regulated industry in meetings; written communication and oral presentations at both Agency and scientific meetings
- Final review authority on communications to external stakeholders that are developed within OCTGT and the Office of Communication, Outreach and Development
- Lead Division activities related to hiring, evaluations, assignments, timekeeping, and staff development
- Lead professional development and provide mentorship of Division staff

Selected Accomplishments:

- Leader and developer of day two of Food and Drug Administration's Emerging Infectious Diseases Workshop held 5/11-12/2010; developed broad research agenda to advance science related to donation of cells, tissues and organs
- OCTGT lead to FDA Multi-Center Working Group determining FDA policy position for banked human milk—group activities include research and review of relevant issues, multiple Commissioner briefings, developing Consumer Advisory for FDA website, organizing full-day discussion at the Pediatric Advisory Committee 12/6/2010; Obtained information necessary to advise and communicate Agency position regarding oversight of Human Milk Banks
- Initiator, leader and developer of newly-formed OCTGT Emerging Infectious Diseases Working Group (EID WG) whose goal is to develop new systematic approach to evaluating emerging infectious diseases, related Office policy, and new policy initiatives related to cell and tissue donor screening and testing—including workshop organization, organize and lead working group, develop research capabilities in cell and tissue communities; EID WG is comprised of members from three Offices within CBER; WG responsible for all cell and tissue donation-related policy development for the Center

- FDA representative to the 2nd Donor-Derived Consensus Conference held 5/1/2010 to evaluate the testing of solid organ donors to prevent the transmission of West Nile Virus (sponsored by the American Society of Transplantation Infectious Disease Community of Practice); Conference outcome will communicate via publication to the organ transplant community recommendations regarding WNV testing of potential organ donors
- First O-5 Acting as Team Commander of a Rapid Deployment Force and Unified Command in field training exercise—August 2010 (planning began Feb 2010); resulted in both training of team members and provision of public health services and direct medical care to a rural underserved community in Erwin, TN

10/2002-3/2010 Medical Officer, DHT, OCTGT, CBER, FDA

Major Duties:

- Subject matter expert, leader and nationally recognized authority on issues related to human cell and tissue donor screening and testing, and regulatory review of donor screening test kits used to test deceased tissue donors
- Develop regulatory documents—including published Guidances and [unpublished] policy options documents
- Lead OCTGT efforts in surveillance and evaluation of Emerging Infectious Diseases
- Lead DHT/OCTGT reviewer for Investigational New Drug applications (IND), Biologic License Applications (BLA), and BLA supplements for test kits with infectious disease screening claims for use with cadaveric specimens or from living donors of human cells or tissue
- Team leader responsible to train and review work of other DHT personnel in review of tests with infectious disease screening claims for use with specimens obtained after the cessation of the heartbeat, or from living donors of human cells or tissue
- Lead monthly Centers for Disease Control and Prevention (CDC)/FDA conference calls designed to facilitate and coordinate interagency issues of mutual interest related to tissue transplantation, improve communication between the two agencies; identify issues to be discussed, developing agenda, and leading the meetings
- Oversight of ongoing post-marketing safety of human tissues. Related duties include participation as a member of CBER's Tissue Safety Team and serving as the backup for completing Health Hazard Evaluations (HHEs) for recalled human tissues.
- Provide expert educational support and technical advice within FDA and to other stakeholders, including regulated industry, for any matters relating to human tissues
- CBER liaison to professional and governmental organizations
- CBER point person for development of FDA's human breast milk regulatory policy
- CBER lead in receiving and evaluating industry requests for exemptions and alternatives to FDA regulations under 21 CFR 1271
- Develop response to public inquiries regarding matters related to human tissues
- Interface with other Department of Health and Human Services agencies (including CDC, Health Resources and Services Administration, Advisory Committee on Blood Safety and Availability) representing CBER/FDA interests at the interagency level

- Train/mentor colleagues new to DHT

Selected Accomplishments:

- Leader in developing content/agenda for numerous advisory committee meetings and public workshops, most recently
 - Developed all agenda items and invited all speakers for cell and tissue-related topics for the “Emerging Arboviruses: Evaluating the Threat to Transfusion and Transplantation Safety” workshop held 12/14-15/2009
 - Developed topic for discussion and Issue Summary, and coordinated recruitment of speakers and special government employees for advisory committee consideration of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* at the Cellular, Tissue and Gene Therapies Advisory Committee held 5/14-15/2009
- FDA representative to Donor-Derived Infection Consensus Conference held in April 2009; conference objective to provide feasible and practical guidelines for nucleic acid amplification testing of organ donors for HIV, HCV and HBV (co-sponsored by American Society of Transplantation, American Society of Transplant Surgeons, Canadian Society of Transplantation, the United Network for Organ Sharing, and the American Association of Tissue Banks)
- Leader (document champion) for numerous guidance documents, including finalizing “Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)” (published 2007): Leadership role in guidance development and finalization includes review of public comments, chair committee meetings for Center-wide evaluation, coordinate decision-making on response to public comments, document revision, ensure the document moves smoothly through the publication process, and negotiate comments and revisions as the document moves through the Center and Agency
- Developed standard operating procedures for completing Health Hazard Evaluations (HHEs), and created a database of all HHE information and decisions

9/2001-10/2002 Medical Officer, Human Tissue Staff, Office of Blood Research and Review, Center for Biologics Evaluation and Research, Food and Drug Administration

- Major duties discussed above. Change in Office was due to administrative changes within CBER

8/2000-9/2001 Medical Officer, Food and Drug Administration Center for Biologics Evaluation and Research, Office of Communication, Training, and Manufacturer’s Assistance (OCTMA), Consumer Affairs Branch (CAB)

Major Duties:

- Communication of Agency policy, regulation and product information to external stakeholders seeking information from the agency (telephone, mail and email)

- Sole medical expert responding to inquiries from health care providers
- Provision of medical expertise to other OCTMA staff
- Primary author of draft Q&A documents for use as Center-wide responses to inquiries about important product issues, such as product shortages or recalls
- Leader in developing CBER program for outreach to healthcare providers
- Primary author of consumer information materials
- CBER public affairs representative at professional meetings

5/18/1997 Residency Training Billet

7/8/1993 Call to Duty as USUHS Medical Student

5/4/1992 Sanitarian COSTEP (Commissioned Officer Student Training and Externship Program) in Indian Health Service (IHS), Belcourt, ND

5/13/91-8/18/91 Sanitarian COSTEP in IHS, Philadelphia, MS

OTHER PROFESSIONAL EXPERIENCE AND OUTSIDE ACTIVITIES

8/13/2010 PHS Recruitment event at East Tennessee State University

- Co-planned event in conjunction with OFRD training event

3/2009-present Mentorship of LT Elizabeth Lybarger

2006-present USPHS Rapid Deployment Force (RDF) Team-2

1/2010-present Deputy Commander/Chief Medical Officer, RDF-2

- Senior medical advisor to Commander, RDF-2
- Senior Command Staff of Tier 1 Team; >105 officers
- Acting Commander for planning (2/2010-8/2010) and execution of OFRD Field Training 10-17 August 2010

4/1/09-1/2010 Director, Medical Services Branch

- Organize and manage the largest Branch within the RDF for training and deployment activities
- Supervise approximately 50-60 officers (all team nurse, physician, mid-level practitioner, mental health, and laboratory providers)
- Monthly Sitreps

2006-3/31/2009 Team Leader, Team Health Section

- Original developer of Team Health Section
- Developed Team Health SOPs and forms
- Provided medical care for all participating officers at Camp Bullis training (8/2007) and during Gustav/Ike Deployment (9/2008)

2000-present Assistant Professor of Medicine, Uniformed Services University of the Health Sciences

2000-present Instructor of Pathology, Uniformed Services University of the Health Sciences

5/2001-present Internal Medicine Staff, Walter Reed Army Medical Center, Washington, DC
7/2000-7/2002 Internal Medicine Staff, National Naval Medical Center, Bethesda, Maryland

COMMITTEES

8/2010-present MSM Working Group of the Advisory Committee on Blood Safety and Availability within the Office of the Assistant Secretary for Health
5/1/2010 FDA Liaison to [Organ] 2nd Donor-Derived Consensus Conference
12/14-15/2009 Scientific Committee for Workshop: Emerging Arboviruses: Evaluating the Threat to Transfusion and Transplantation Safety
3/2009-present FDA Liaison to National Coalition for Oversight of Assisted Reproductive Technologies
5-6/2009 FDA Liaison to [Organ Donor] HTLV Advisory Group
3/23/2009 FDA Liaison to [Organ] Donor Derived Consensus Conference
9/2008-present OCTGT Liaison to AABB Transfusion Transmitted Diseases Committee
10/2001-present Commissioned Corps Awards Review Committee
11/2002-present FDA Research Involving Human Subjects Committee; CBER Alternate Member
9/2004-present CBER Tissue Safety Team
1/2007-5/2007 Course Advisory Group Member for Human Tissue Establishment Inspections Course
2006-present Public Health Service Blood Emerging Infectious Diseases Working Group
8/2006-present FDA Liaison to American Association of Tissue Banks UDHQ-OTE Project (Uniform Donor History Questionnaire for Organ, Tissue and Eye Donors)
3/2006-present Transplantation Transmission Sentinel Network (TTSN) Advisory Group; FDA representative
6/28/2007 USPHS Medical Review Board
1/2007-5/2007 Course Advisory Group Member for Human Tissue Establishment Inspections Course held 7-10 May 2007
2006-present Public Health Service Blood Emerging Infectious Diseases Working Group
8/2006-present FDA Liaison to American Association of Tissue Banks (AATB) UDHQ-OTE Project (Uniform Donor History Questionnaire for Organ, Tissue and Eye Donors)
3/2006-5/2009 Transplantation Transmission Sentinel Network (TTSN) Advisory Group; FDA representative

- Member of Working Group for Part B of the TTSN system development
- Member of Working Group for Part C of the TTSN system development

9/2004-present	CBER Tissue Safety Team
10/2001-3/2010	CBER Commissioned Corps Awards Review Committee
11/2002-3/2010	CBER co-representative to FDA Research Involving Human Subjects Committee
10/2003-2005	OCTGT alternate representative to CBER Counter Terrorism Coordinating Council (CTCC)
8/2003-2006	CBER Liaison to AATB Good Tissue Practices Guidance Task Force
8/2003-10/2003	Course Advisory Group (CAG) Member for Human Tissue Establishment Inspections Course held 10/20-24/2003
3/2003-present	FDA Liaison to AATB Standards Committee
11/2001-present	FDA Liaison to Eye Bank Association of America (EBAA) Medical Advisory Board

PROFESSIONAL ORGANIZATIONS

2007-present	The Association of Military Surgeons of the United States
2002-present	Commissioned Officer Association
1993-2001	American Medical Association Delegate, AMA-Medical Student Section, 1995-7
1997-2001	American College of Physicians (ACP)
1993-1997	Medical and Chirurgical Faculty of Maryland; Delegate, 1994-7

CAREER PROGRESSION

3/14/2010	Change of Billet to Supervisor Regulatory Operations Officer (O-6 Billet)
8/18-20/2009	Office of Force Readiness and Deployment (OFRD) – 56 th Presidential Inauguration
8/29-9/16/2008	OFRD Deployment – Hurricanes Gustav and Ike
5/17/2007	Promotion to Permanent Grade O-4
12/2006	OFRD Deployment – Ford State Funeral
7/2006	Promotion to Temporary Grade O-5
6/2006	Member of USPHS Rapid Deployment Force Team-2 <ul style="list-style-type: none">• Deputy Commander (January 2010-present)• Director, Medical Services Branch (March 2009-January 2010)• Team lead for Team Health (2006-March 2009)
12/05/2005	Change of Billet to Director Regulatory Operations Officer (O-6 Billet)
9/1-15/2005	OFRD Deployment – Hurricane Katrina
12/2004	FDA Nominee for Exceptional Proficiency Promotion (EPP)
6/9-10/2004	OFRD Deployment – Reagan State Funeral
2003	OFRD Basic Readiness Standards Completed
4/24/2003	Change of Billet to Senior Regulatory Operations Officer (O-5 Billet)

10/1/ 2002 Assignment to Office of Cellular, Tissue and Gene Therapies
Division of Human Tissues, Human Tissue and Reproduction
Branch

9/12/2001 Commissioned Corps Readiness Force (CCRF) Deployment –
Terrorist Response, NNMC Backfill during USNS Comfort
Deployment

9/9/2001 Assignment to Office of Blood Research and Review, Immediate
Office of Director, Human Tissue Staff

7/1/2001 Promotion to Temporary Grade O-4

3/10-3/25/2001 CCRF Deployment to Mescalero Indian Hospital, Mescalero, NM
2001
Joined Commissioned Corps Readiness Force

7/16/2000 Assignment to Center for Biologics Evaluation and Research,
Office of Communication, Training and Manufacturers Assistance,
Division of Communication and Consumer Affairs, Consumer
Affairs Branch

Promotion to Permanent Grade O-3
Senior Health Promotion Officer Billet (O-5 Billet)

5/18/1997 Residency Training Billet

5/17/1997 Assimilation to PHS Regular Corps

7/8/1993 Call to Duty as USUHS Medical Student

5/4/1992 Sanitarian COSTEP in IHS, Belcourt, ND

5/13/91-8/18/91 Sanitarian COSTEP in IHS, Philadelphia, MS

* Geographic mobility is not conducive for FDA regulatory professional development.

PHS AWARDS

01/29/2010 PHS Special Assignment Award

12/23/2009 Unit Commendation

12/10/2009 **Commendation Medal** for “Noteworthy technical and
professional contributions to USPHS Rapid Deployment Force
Team 2 (PHS-2 RDF) as the leader of Team Health during the
Gustav/Ike deployment”

12/15/2008 Crisis Response Service Award for “Deployment for Hurricanes
Gustav and Ike Response”

10/16/2008 Outstanding Unit Citation for “Developing and publishing a final
guidance on donor eligibility for human cells and tissue intended
for transplantation”

04/16/2008 Outstanding Unit Citation for “Extraordinary and collaborative
efforts in responding to the public health threat posed by
potentially unsafe human tissue products in commerce.”

12/28/2007 Unit Commendation for “Outstanding voluntary contributions to
ensure a professional and successful retirement ceremony for
RADM Marlene Haffner on December 14, 2006.”

10/10/2007 Outstanding Unit Citation for “Outstanding contributions to improving the safety of blood and blood products through the licensing of new assays to screen for hepatitis B infection.”

9/10/2007 Field Medical Readiness Badge

7/31/2007 Unit Commendation for “The dedicated and innovative review of the first multiplex nucleic acid donor screening assay for the detection of HIV-1, HCV and HBV.”

1/24/2007 Outstanding Unit Citation for “Exemplary contributions to protect the public health of the citizens of Louisiana, Texas, Florida, and Mississippi after hurricanes Katrina, Rita, and Wilma.”

1/5/2007 Unit Commendation for “Outstanding teamwork and exceptional performance related to the implementation of the new regulations for human cells, tissues, cellular and tissue-related products (HCT/Ps)”

5/17/2006 Unit Commendation for “Excellence in development and implementation of a new, effective and consistent inter-office approach to address adverse reaction reports for human cells and tissues”

2/23/2006 **Outstanding Service Medal** for “Continuous outstanding leadership in the review and compliance activities of the Division of Human Tissues (DHT), Office of Cellular, Tissue and Gene Therapies (OCTGT)”

1/23/2006 Crisis Response Service Award

6/24/2005 Unit Commendation for “Providing exceptional medical and public health services for the DC Department of Health for the Reagan State Funeral”

1/7/2005 Outstanding Unit Citation for “Outstanding efforts in the use of an investigational test to screen the Nation’s blood supply and to ensure its safety during the West Nile Virus epidemic”

12/22/2004 Commissioned Corps Training Ribbon

7/14/2003 Outstanding Unit Citation for “Outstanding effort in addressing the maintenance of the safety of the nation’s blood supply during the West Nile Virus infection epidemic”

4/18/2003 Unit Commendation for “Exceptional performance in protecting the public health through collaborative efforts between FDA components and the CDC regarding the safety of human tissue for transplantation”

3/10/2003 **Achievement Medal** for “Publication of draft guidance to prevent transmission of Creutzfeldt - Jakob disease (CJD) and variant Creutzfeldt-Jakob disease (vCJD) by human tissues intended for transplantation”

9/6/2002 Outstanding Unit Citation for “Outstanding service to the people of the United States in responding to terrorist attacks”

2/14/2002 Crisis Response Service Award

5/3/2001 Outstanding Unit Citation for “Helping avert a major influenza virus vaccine shortage and helping PHS agencies, health

practitioners, and the general public cope with delayed availability”

1/1/1998 Bicentennial Unit Commendation
5/17/1997 Regular Corps Ribbon

NON-PHS AWARDS

7/24/2009 FDA Group Recognition as a member of the Cobas TaqScreen MPX Test Review Team for “Exceptional review accomplishment in licensing the first donor screening test to detect HIV-1 Group O RNA and HIV-2 RNA, the Cobas TaqScreen MPX test”
5/25/2005 Secretary’s Award for Distinguished Service as member of the “Tissue Action Plan Team”
7/21/2004 Secretary’s Award for Distinguished Service as member of the “West Nile Virus Blood Screening Group”
1/2004 Navy Meritorious Unit Commendation

PUBLIC HEALTH TRAINING

11/9-10/2010 CBER Human Resources for Managers
10/7/2010 Managing Time and Multiple Priorities within CBER’s Regulatory Environment
9/28/2010 OFRD Team Leader Conference
9/13-14/2010 34th Annual Meeting of the American Association of Tissue Banks
8/25/2010 FDA/CBER Coaching Roundtable 2010: How to Mentor Employees
8/10-17/2010 OFRD Field Training: Erwin, TN
8/2-4/2010 35th Annual Meeting of NATCO, The Organization for Transplant Professionals
6/15-18/2010 27th Annual Meeting of the Association of Organ Procurement Organizations
6/2-5/2010 49th Annual Meeting of the Eye Bank Association of America
5/1-3/2010 American Transplant Congress 2010
3/20-23/2010 14th Annual Spring Meeting of the American Association of Tissue Banks
3/10-14/2010 American Board of Internal Medicine Review Course
12/14-15/2009 Emerging Arboviruses: Evaluating the Threat to Transfusion and Transplantation Safety
10/29-11/1/2009 47th Annual Meeting of the Infectious Diseases Society of America
10/17-21/2009 65th Annual Meeting of the American Society for Reproductive Medicine
9/13-17/2009 33rd Annual Meeting of the American Association of Tissue Banks
8/16-22/2009 OFRD Field Training: Ft. AP Hill
6/17-20/2009 48th Annual Meeting of the Eye Bank Association of America
3/29-31/2009 13th Annual Spring Meeting of the American Association of Tissue Banks

1/28-30/2009	5 th Annual FDA and the Changing Paradigm for HCT/P Regulation
1/18/2009	Special Training Session for the 2009 Presidential Inauguration National Mall Medical Response Teams
10/20-22/2008	NIH Consensus Development Conference: Hepatitis B
10/2/2008	CBER/CDRH Best Practices Workshop
6/4-7/2008	Eye Bank Association of America Annual Meeting 2008
5/3-5/2008	American Association of Tissue Banks Donor Suitability Workshop
4/29-5/1/2008	American Association of Tissue Banks 12 th Annual Spring Meeting
1/9-11/2008	4 th Annual FDA and the Changing Paradigm for HCT/P Regulation
9/26-28/2007	7 th Annual Somatic Cell Therapy Symposium
9/16-18/2007	American Association of Tissue Banks 31 st Annual Meeting
6/24-26/2007	American Association of Tissue Banks Donor Suitability Workshop
6/20-22/2007	2007 Annual Meeting of the Eye Bank Association of America
6/5-6/2007	Organ and Tissue Safety Workshop 2007: Advances and Challenges
8/20-24/2007	Basic Disaster Life Support Course; Threats and Viable Solutions for Healthcare Disaster Preparedness; Preventing and Responding to Suicide Terrorism for First Responders and Receivers---OFRD Field Training at Camp Bullis, Texas
5/23-27/2007	Medical Effects of Ionizing Radiation Course
3/27/2007	American Association of Tissue Banks 11 th Annual Spring Meeting
12/12-13/2006	Institute of Medicine: Infectious Disease Surveillance and Detection: Assessing the Challenges – Finding Solutions
11/16-18/2006	Quality Assurance Workshop VIII
11/2006	Completed 4 required National Incident Management System/ FEMA Emergency Management Institute online training modules
10/13/2006	Situational Leadership
9/25-26/2006	International Society for Cellular Therapy Somatic Cell Therapy Symposium
11/2005	Completed all OFRD Online Physician Modules
11/16-17/2005	IBC Life Science's Second Annual Transmissible Spongiform Encephalopathies (TSE): Science and Strategies to Detect and Control Infectivity in Biopharmaceuticals and Blood Products
9/30/2005	Finalizing Review Practice Harmonization Documents for Migration Studies and 510(k) Submissions for External Controls, and Identification of Future Areas for Harmonization
12/2004	Independent Officer Training Course Completed (IOTC)
9/14-16/2004	Basic Officer Training Course (BOTC)
6/24-25/2004	3 rd Annual Joint CBER/CDRH Reviewer Best Practices Workshop
2003	All OFRD Core and Optional Online Training Modules Completed

9/30-10/1/2003 National Academy of Sciences, Institute of Medicine (IOM)
Meeting: "Learning from SARS: Preparing for the Next Disease
Outbreak."
7/25/2003 CBER Medical Device Training
2/24-28/2003 Combined Humanitarian Assistance Response Training (CHART)
9/12/2002 Completed CBER "Symposia in Clinical Trials" course
9/18-19/2002 Evidence Based Assisted Reproductive Technologies
8/14-15/2002 Adapting to a Changing Global Environment, 5th Annual Force
Health Protection Conference and 2nd Annual DOD Population
Health and Health Promotion Conference (held 8/9-16/2002)
6/10-12/2002 NIH Consensus Development Conference: Management of
Hepatitis C: 2002
12/11/2001 CBER Education Forum: Assay Validation Case Study
10/23-24/2001 The Policies and Science of Prions and Plasma
10/15/2001 Trauma Survival: Overcoming the Psychological Scarring
4/2-4/2001 Reviewer Training: Introduction to the Regulatory Process
10/5-6/2000 Workshop on Vaccine Communication
9/20-22/2000 International Workshop on Diagnostics for Transmissible
Spongiform Encephalopathies (TSEs)
7/31-8/4/2000 Food and Drug Law Course
7/1993 3 Week Commissioned Corps Training Course prior to starting
USUHS

PUBLICATIONS

The Food and Drug Administration. Draft Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Whole Blood and Blood Components for Transfusion and Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps). 3/2009. (Document Co-Champion/Co-Author)

The Food and Drug Administration. Draft Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Donors of Whole Blood and Blood Components Intended for Transfusion and Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps). April 25, 2008. (Document Co-Champion/Co-Author)

Enhancing Transplant Safety: A New Era in the Microbiologic Evaluation of Organ Donors? American Journal of Transplantation. Dec 2007; 7: 2652-2654. PMID: 17983389

Invasive Group-A Streptococcal Infection in an Allograft Recipient. The Journal of Bone and Joint Surgery. September 2007; 89:2044-7. PMID: 17768205

The Food and Drug Administration. Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products. August 8, 2007. (Document champion/principal author).

The Food and Drug Administration. Guidance for Industry: Recommendations for Obtaining a Labeling Claim for Communicable Disease Donor Screening Tests Using Cadaveric Blood Specimens from Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps). November 12, 2004. (principal author/document champion).

The Food and Drug Administration. Draft Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps). Federal Register. 2004; 69(101): 29835. (principal author/document champion).

CDC. Invasive *Streptococcus pyogenes* After Allograft Implantation --- Colorado, 2003. Morbidity and Mortality Weekly Report. 2003; 52:1173-1176. Reported by:

The Food and Drug Administration. Draft Guidance for Industry: Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps). Federal Register. 2002; 67:42789. (principal author).

Rituximab Therapy in Hematologic Malignancy Patients with Circulating Blood Tumor Cells: Association with Increased Infusion-Related Side Effects and Rapid Blood Tumor Clearance. Journal of Clinical Oncology. 1999; 17:791-795. PMID: 10071268

PRESENTATIONS

7 December 2010. “Donor Eligibility Rule.” “Donor Eligibility—Donor Testing.” and “Donor Eligibility—Donor Screening.” At Inspection of Human Cells, Tissues, and Cellular and Tissue-Based Product (HCT/Ps) Establishments (BI206) in Rockville, MD held 6-10 December 2010.

6 December 2010. “Donor Screening Consideratoins for Donors of Human Tissues.” At Pediatric Advisory Committee Meeting in Bethesda, MD held 6-7 December 2010.

29 October 2010. “Review and Licensure of Tissue Donor Screening Tests in the United States.” At Asian Pacific Association of Surgical Tissue Banking 2010 Congress in Bikittinggi, West Sumatra, Indonesia held 27-30 October 2010.

14 September 2010. “FDA Initiatives for Evaluating Emerging Infectious Diseases.” At American Association of Tissue Banks Annual Meeting in National Harbor, MD held 11-14 September 2010.

26 July 2010. “FDA EID Workshop: Day 2 Organs, Tissues and Cells.” At Blood Products Advisory Committee in Gaithersburg, MD held 26-27 July 2010.

- 9 July 2010. "FDA Regulation of Human Cells and Tissues." At West Nile Virus: Scientific Considerations for Tissue Donors workshop sponsored by the American Association of Tissue Banks in McLean, VA held 9 July 2010.
- 10 June 2010. "Cell and Tissue Donor Screening." At Advisory Committee on Blood Safety and Availability meeting in Gaithersburg, MD held 10-11 June 2010.
- 5 June 2010. "Evaluating Emerging Infectious Diseases at FDA." At Eye Bank Association of America Annual Meeting in Hilton Head, SC held 2-5 June 2010.
- 12 May 2010. "Regulatory Framework: Evaluating Infectious Disease Risks in Human Cells, Tissues and Cellular and Tissue-Based Products." At FDA Emerging Infectious Diseases Workshop in Gaithersburg, MD held 11-12 May 2010.
- 23 March 2010. "Donor Eligibility Issues for Reproductive HCT/P Facilities." At American Association of Tissue Banks Spring Meeting in Hollywood, CA held 20-23 March 2010.
- 20 March 2010. "FDA Regulations Related to Pre-Processing Cultures." At Physicians Council Meeting, part of American Association of Tissue Banks Spring Meeting in Hollywood, CA held 20-23 March 2010.
- 8 March 2010. "Donor Eligibility for Cord Blood Donors: Selected Topics." At Cord Blood Licensure: A Workshop in Rockville, MD held 8-9 March 2010.
- 23 February 2010. "Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)—Donor Screening" "Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products—Donor Testing" and "Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps): Donor Eligibility Rule." At Human Tissue Establishment Training Course held in Rockville, MD at Office of Regulatory Affairs University held 21-25 February 2010.
- 16 January 2010. "Available Relevant Medical Records." At American Association of Tissue Banks Donor Suitability Workshop IV in McLean, VA held 16-18 January 2010.
- 2 December 2009. "Human Milk Banking" to Office of Cellular Tissues and Gene Therapies.
- 20 October 2009. "FDA: Donor Eligibility Issues." At 65th Annual Meeting of the American Society for Reproductive Medicine held in Atlanta, GA 17-21 October 2009.
- 21 September 2009. "Ask the FDA." At 33rd Annual Meeting of the American Association of Tissue Banks in Las Vegas, NV held 17-21 September 2009.

20 June 2009. "FDA, Legal, EBAA Medical Standards Panel" At 48th Annual Meeting of the Eye Bank Association of America in Seattle, WA held 17-20 June 2009.

14 May 2009. "*Chlamydia trachomatis* and *Neisseria gonorrhoeae* transmission by HCT/Ps recovered from the reproductive system, gestational tissues, or other sources: Introduction." At Cell, Tissue and Gene Therapies Advisory Committee in Gaithersburg, MD held 14-15 May 2009.

30 March 2009. "FDA Update." At 13th Annual Spring Meeting of the American Association of Tissue Banks in Orlando, FL held 29-31 March 2009.

29 January 2009 "Donor Eligibility: Special Issues." At Pharma Conference: 5th Annual FDA and the Changing Paradigm for HCT/P Regulation in Las Vegas, NV held 28-30 January 2009.

10 January 2009. "Available Relevant Medical Records." American Association of Tissue Banks Donor Suitability Workshop in Reston, VA held 10-12 January 2009.

28 October 2008. "Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/)*s*—Donor Screening" "Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/)*s*—Donor Eligibility Rule" "Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/)*s*—Donor Testing" and "Plasma Dilution." At HCT/P Establishment Inspection Course in Rockville, MD held 27-31 October 2008.

24 October 2008. "Donor Screening Tests vs. Diagnostic Tests." At ICAAC/IDSA Annual Meeting, Workshop entitled "Optimizing Screening of Organ and Tissue Donors for Transplantation: New Technologies and Future Directions" in Washington, DC held 24-28 October 2008.

21 October 2008. "Donor Testing for FDA-Regulated Products." For Transplant News Audioconference held 21 October 2008.

7 June 2008. Co-Panelist and presenter for "Regulatory Issues Panel: FDA-EBAA-Legal." At Eye Bank Association of America Annual Meeting 2008 in Hollywood, FL held 4-7 June 2008.

3 May 2008. "Available Relevant Medical Records." At American Association of Tissue Banks Donor Suitability Workshop in Reston, VA held 3-5 May 2008.

9 May 2008. "Donor Eligibility: Selected Topics for the Discriminating Reviewer." To Division of Cell and Gene Therapies, Office of Cellular Tissue and Gene Therapies.

1 May 2008. "West Nile Virus (WNV) and Donors of Human Cells, Tissues and Cellular and Tissue-Based Products (HCT/Ps)" and "Trypanosoma cruzi and Donors of Human

Cells, Tissues and Cellular and Tissue-Based Products (HCT/Ps).” At Blood Products Advisory Committee Meeting in Rockville, MD held 1-2 May 2008.

1 April 2008. “5 Layers of [Blood] Safety.” At American Association of Tissue Banks 12th Annual Spring Meeting in Savannah, GA held 29 March – 1 April 2008.

9 January 2008. “Donor Eligibility.” At 4th Annual FDA and the Changing Paradigm for HCT/P Regulation in San Antonio, TX held 9-11 January 2008. Co-moderator for 2 workshop sessions entitled “Donor Eligibility.”

26 September 2007. “Update on Donor Issues.” At 7th Annual Somatic Cell Therapy Symposium in Bethesda, MD held 26-28 September 2007.

18 September 2007. “FDA Update.” At American Association of Tissue Banks 31st Annual Meeting in Boston, MA held 14-18 September 2007.

25 June 2007. “Available Relevant Medical Records.” At American Association of Tissue Banks Donor Suitability Workshop in Reston, VA held 24-26 June 2007.

5 June 2007. “FDA Adverse Event Reporting for HCT/Ps.” At Organ and Tissue Safety Workshop 2007: Advances and Challenges in Reston, VA held 5-6 June 2007.

7-8 May 2007. “Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps): Donor Eligibility Rule.” “Donor Screening.” “Donor Testing.” “Plasma Dilution.” At HCT/P Establishment Inspection Course in Rockville, MD held 7-10 May 2007.

26 April 2007. “Issues Related to the Potential Transmission of *Trypanosoma cruzi* by Human Cells, Tissues, and Cellular and Tissue-Based Products.” At Blood Products Advisory Committee meeting in Gaithersburg, MD held 26 April 2007. Also presented 14 September 2007 at AATB 31st Annual Meeting in Boston, MA held 14-18 September 2007.

27 March 2007. “Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).” “FDA Update.” At American Association of Tissue Banks 11th Annual Spring Meeting in Hollywood, CA held 23-27 March 2007.

17 November 2006. “FDA Update.” At American Association of Tissue Banks Quality Assurance VIII conference in San Francisco, CA held November 16-18, 2006.

26 September 2006. “Donor Issues Scenario-Based Panel” and “FDA Introduction.” At International Society for Cellular Therapy’s Somatic Cell Therapy Symposium in Bethesda, MD held September 25-27, 2006.

6 June 2006. "HCT/P Regulatory Framework." At Transplantation Transmission Sentinel Network Advisory Group Meeting in Reston, VA held June 6, 2006.

8 March 2006. "FDA's Current Recommendations on Behavior-Based HCT/P Donor Deferrals." Presented for Dr. Ruth Solomon at Workshop on Behavior-Based Donor Deferrals in the Era of Nucleic Acid Testing (NAT) in Bethesda, MD held March 8, 2006.

4 March 2006. "Testing Donors of Human Cells and Tissues." America's Blood Centers in Houston, TX (via video teleconference).

14 February 2006. "Donor Eligibility Determination for Donors of Human Cells, Tissues and Cellular and Tissue-Based Products (HCT/Ps)." Introduction to Inspection of Human Cells, Tissues & Cellular and Tissue Based Product (HCT/P) Establishments in Rockville, MD held February 13-16, 2006.

8 February 2006. "Testing Donors of Human Cells and Tissues." 2nd Annual FDA and the Changing Paradigm for Tissue Regulation in Las Vegas, NV held February 8-10, 2006.

17 November 2005. "TSE Control in Tissue Donor Screening and Tissue Practices" at IBC Life Science's Second Annual Transmissible Spongiform Encephalopathies (TSE): Science and Strategies to Detect and Control Infectivity in Biopharmaceuticals and Blood Products in Reston, VA held November 16-17, 2005.

20 September 2005. "Update on Donor Screening for TSEs" at American Association of Tissue Banks (AATB) Annual Meeting in Hollywood, FL held 17-20 September 2005.

Wrote "Donor Eligibility" for American Association of Bioanalysts Meeting: Implementing FDA Regulations in Your Reproductive Establishment: Are You Ready for the FDA Inspectors? in Baltimore, MD held 10-11 September 2005. Presented by Martha Wells because of officer's unavailability due to Katrina deployment.

2 June 2005. "Current Testing Requirements for Donors of Human Cells and Tissues." Preventing Organ and Tissue Allograft-Transmitted Infection: Priorities for Public Health Intervention hosted by CDC in Atlanta, GA held 2-3 June 2005.

2 June 2005. "New FDA Reporting Regulations for Human Cells, Tissues and Cellular and Tissue-Based Products (HCT/Ps)." Preventing Organ and Tissue Allograft-Transmitted Infection: Priorities for Public Health Intervention in Atlanta, GA held 2-3 June 2005.

25 May, 28 June 2005. "Donor Eligibility Determination for Donors of Human Cells, Tissues and Cellular and Tissue-Based Products (HCT/Ps)." Human Tissue Establishment Inspections Update at Office of Regulatory Affairs University (ORA U) in Rockville, MD held 24-26 May and 27-29 June 2005.

26 May 2005. "US and EU Regulatory Framework." International Plasma Fractionation Association/Paul Erlich Institute (IFPA/PEI) 12th NAT Workshop on Surveillance and Screening of Blood Borne Pathogens in Bethesda, MD held 26-27 May 2005.

11 May 2005. "Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)." In-Vitro Diagnostics Roundtable in Rockville, MD held 11 May 2005.

7 December 2004 "Donor Eligibility for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)." CBER Grand Rounds in Rockville, MD.

12 November 2004. "Donor Eligibility Determination: Selected Topics for Quality Assurance Professionals." American Association of Tissue Banks Quality Assurance VI Workshop in Tempe, AZ held 10-12 November 2004.

20 October 2004. "Donor Eligibility Determination for Donors of Reproductive Cells and Tissues." American Society for Reproductive Medicine Annual Meeting in Philadelphia, PA held 16-20 October 2004.

28 August 2004. "Donor Eligibility Determination for Donors of Reproductive Cells and Tissues." American Association of Tissue Banks 28th Annual Meeting in Chicago, IL held 28-31 August 2004.

13 February 2004. "Minimizing Risk of TSE Agents in Human Tissues." Transmissible Spongiform Encephalopathies Advisory Committee in Silver Spring, MD held February 12-13, 2004.

13 November 2003. "Regulatory Update: Bacterial Transmission and Where the Rules Are." American Association of Tissue Banks Quality Assurance Workshop V in New Orleans, LA held 12-14 November 2003.

21 October 2003. "Screening and Testing of Donors of Human Tissue Intended for Transplantation" and "Donor Testing Issues." FDA Human Tissue Establishment Inspections Training Course in Rockville, MD held 20-24 October 2003.

23 August 2003. "Update on FDA's Regulatory Initiatives: Reproductive Cells and Tissues." American Association of Tissue Banks 27th Annual Meeting in San Diego, CA held 23-26 August 2003.

28 March 2003. "Infections Reported to be Associated with AATB-Accredited Entities: A Panel Discussion" and "Bacterial Culturing of Human Tissue Allografts: AATB Interaction with FDA and CDC Suggestions to the Standards Committee." American Association of Tissue Banks 7th Annual Spring Meeting in Clearwater Beach, FL held 28-31 March 2003.

4 November 2002. "HCT/P Transmission Issues." Workshop on Development of Donor Screening Assays for West Nile Virus in Bethesda, MD held 4-5 November 2002.

27 August 2002. "Workshop: Bacterial Culturing of Human Tissue Allografts (Panel Discussion)." 26th Annual Meeting of the American Association of Tissue Banks in Boston, MA held 23-27 August 2002.

25 July 2002. "Draft Guidance for Industry: Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)." Eye Bank Association of America's Education Institute. Call-in seminar.

26 June 2002. "FDA Draft Guidance on Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Human Cells, Tissues, and Cellular and Tissue-Based Products: Presentation of Draft Guidance." FDA Transmissible Spongiform Encephalopathies Advisory Committee meeting in Gaithersburg, MD held 26-27 June 2002.

4 June 2002. "Draft Guidance for Industry: Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Human Cells, Tissues, and Cellular and Tissue-Based Products." FDA Human Tissue Establishment Inspections Training Course in Laurel, MD held 3-7 June 2003.

RECENT LICENSE/SUPPLEMENT APPROVALS (as Lead Scientific Reviewer)

- 10/22/2009 Cobas TaqScreen West Nile Virus Test (cadaveric claim)
- 9/18/2009 Abbott PRISM HIV O Plus (cadaveric and living donor claims)
- 8/27/2009 Roche MPX BLA 27 (living donor language; cadaveric claim)
- 2/18/2009 Ortho HCV ELISA Test System (cadaveric claim)
- 2/12/2009 Ortho T. cruzi ELISA Test System (cadaveric claim license)
- 8/12/2008 Procleix Ultrio - (pooled testing claim for HPC donors)
- 4/2/2008 Cobas TaqScreen West Nile Virus Test (cadaveric claim)
- 1/15/2008 Abbott HTLV-I/II EIA (living donor language only)
- 8/16/2007 COBAS AmpliScreen HBV Test (pooled testing claim for HPC donors)
- 5/23/2007 COBAS Ampliscreen HIV-1 Test, V 1.5 (pooled testing claim for HPC donors)
- 5/22/2007 COBAS Ampliscreen HCV Test Version 2.0 (pooled testing claim for HPC donors)

PEER-REVIEW

- 2010 Schwartz, BS; Paster, M; Ison, MG; and Chin-Hong, PV. Organ Donor Screening Practices for Trypanosoma cruzi Infection among U.S. Organ Procurement Organizations. American Journal of Transplantation.
- Huang, R. and Fishman, J. Screening of Deceased Organ Donors: Challenges with Improved Technology. American Journal of Transplantation.
- 2007 Yao, F.; et al. The Risk of HIV, HBV, HCV, and HTLV Infection Among Musculoskeletal Tissue Donors in Australia. American Journal of Transplantation. 2007; 7: 2723-2726.