Melissa A. Greenwald, MD
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PROFESSIONAL EXPERIENCE

National leader in organ, blood stem cell, and tissue transplantation. International subject matter expert in clinical and laboratory evaluation of donors of substances of human origin for clinical application. Developed policy for clinical safety in the use of organs, tissues, cells and blood products. Experienced in policy development across multiple government Agencies. Experienced in working with diverse transplantation (organ and tissue) and transfusion (blood, blood stem cells) stakeholder communities, including government, industry, and clinical sectors—domestically and internationally. Demonstrated leader in staff development, supervision, policy development and program management. Skilled at determining program needs and goals and developing effective, comprehensive solutions.

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

2023	Nevada Medical Doctor – Administrative License #24265
2021	Association for the Advancement of Medical Instrumentation, Process Validation Requirements & Industry Practice
2020	Lab Director CME Course Program, COLA
2020	Florida Medical License ME 144201
2019	Utah Physician License 11565231-1205
2019	Texas Physician License AM00135
2019	Arkansas Physician License E-12248
2018	Colorado Physician License DR.006059
2018	Fellow, American Society of Transplantation (FAST)
2016	Louisiana Physician License 303740
2016	Alabama Physician License MD35052

2013	American Society of Quality, Certified Manager of Quality/Organizational Excellence
2012	Basic Life Support
2010	American Board of Internal Medicine Maintenance of Certification
2000	American Board of Internal Medicine Board Certification
1999	Washington, DC Physician License MD31800
1999	National Board of Medical Examiners (Parts 1, 2, 3)

AFFILIATIONS

5/2023-Present	Donor Services Laboratory
1/2024-Present	Laboratory Director, Tampa FL
10/2022-Present	Chief Medical Officer, American Association of Tissue Banks
02/2022-Present	Medical Director, DiscGenics
07/2022-Present	Chief Medical Officer, 34 Lives
08/2021-10/2022	Medical Consultant, American Association of Tissue Banks
02/2021-06/2022	Chief Medical Officer, Peripheral Thereutics (Solaxa), Maryland
11/2020-12/2022	Medical Director, Right Cells Biologics, Utah
12/2020-Present	Laboratory Director, Donor Alliance CLIA # 06D0921245
12/2019-5/2023	Associate Laboratory Director, Eurofins DPT, Dallas Laboratory CLIA # 45D2093413
2/2018-4/2020	Scientific and Medical Advisory Board, Generate Life Sciences (formerly California Cryobank Life Sciences/Cord Blood Registry)
07/2017-09/2023	Laboratory Consultant, Eurofins Donor and Product Testing
08/2018-3/2021	Associate Medical Director (Organs), Donor Alliance
03/2018-Present	Principal, MA Greenwald Consulting LLC
01/2018-Present	Adjunct Associate Professor of Medicine, Uniformed Services University School of Medicine
12/2017-4/2020	Regulatory Medical Director, Generate Life Sciences (formerly California Cryobank Life Sciences)
03/2017-12/2021	Consultant Medical Director, MJB and Associates
2000-2/2018	Adjunct Assistant Professor of Medicine, Uniformed Services University School of Medicine

CONSULTING EXPERIENCE

FDA Regulatory Consultation

- Human Cells and Tissues, Devices, Biologics
- 361 vs 351 HCT/Ps
- Inspectional Findings – evaluations and responses
- Regulatory Letters (Warning Letters, Untitled Letters) evaluation and responses
- Teaming with CRO for IND preparation
- Regenerative medicine and organ acquisition
- Quality Compliance and Improvement
- General Regulatory Strategy
- TRG and TRIP Submissions
- Regulatory Analysis Documentation
- Health Hazard Evaluations (Devices)
- Product Launch Preparation
- Review of Risk Assessment Documentation (Devices)

- Startup Regulatory Strategy
- Medical Director Services – Tissue Banking, CLIA Laboratory, Donor Chart Review
- Laboratory Scientific Advisor (Infectious Disease Assays, Regulatory for FDA and CLIA)
- Medical Advisory Boards

COMMITTEES

Organs

6/2020-present	AST Vascular Composite Allotransplantation Advisory Council (VCA AC) Executive Committee
6/2023-present	VCA AC Executive Committee Co-Chair
2/2021-present	Member, Donor Alliance Advisory Board
1/2019-2/2021	Chair, Donor Alliance Advisory Board
4/2018-9/2020	Board of Directors, Donate Life America
11/2011-Present	World Health Organization (WHO)/Centro Nazionale Trapiant (CNT) Project Notify Editorial Board
4/2023-Present	Chair, Infections Editorial Group
2010-2016	Organ Donation Research Consortium
1/30-31/2017	HRSA Liaison to American Society of Transplantation HCV Consensus Conference
2/2016-3/2018	Ex Officio Member, Board of Directors, Donate Life America
12/2015-2/2018	Ex Officio Member, Board of Directors, Organ Procurement and Transplantation Network
5/2013-7/2016	Ex Officio Member, Disease Transmission Advisory Committee (DTAC) of the United Network for Organ Sharing • FDA/DHT 5/2013-8/2014 • HRSA/DoT 9/2014-7/2016 • DTAC Policy Subcommittee 7/2013-7/2016
2011-June 2013	PHS Guideline Revision Working Group
7/28/2011	FDA Liaison to Optimal Testing of the Live [Organ] Donor to Prevent the Transmission of Infectious Diseases Consensus Conference
5/1/2010	FDA Liaison to [Organ] 2nd Donor-Derived Consensus Conference
5-6/2009	FDA Liaison to [Organ Donor] HTLV Advisory Group
3/23/2009	FDA Liaison to [Organ] Donor Derived Consensus Conference

Blood Stem Cells

2/2018-5/2020	Member, Cord Blood Registry Medical and Scientific Advisory Board
10/2016-09/2016	HRSA Member of NIH Blood and Marrow Transplantation Late Effects Steering Committee Member: Health Care Delivery Working Group
1/2016-2/2018	Ex Officio Member, Board of Directors, National Marrow Donor Program (NMDP)

10/2014-7/2016	Ex Officio Member, National Marrow Donor Program Donor and Patient Safety Monitoring Advisory Group
10/2014-7/2016	Ex Officio Member, NMDP Histocompatibility Advisory Group

Tissues

2/2019-09/2022	American Association of Tissue Banks Standards Committee Member (representing Physicians Council)
3/2009-8/2014	FDA Liaison to National Coalition for Oversight of Assisted Reproductive Technologies
9/2004-8/2014	CBER Tissue Safety Team
1/2007-5/2007	Course Advisory Group Member for Human Tissue Establishment Inspections Course held 7-10 May 2007
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
3/2003-8/2014	FDA Liaison to AATB Standards Committee
11/2001-8/2014	FDA Liaison to Eye Bank Association of America (EBAA) Medical Advisory Board

Blood

8/2010-10/2015	MSM Working Group (HHS) • FDA/DHT 8/2010-8/2014 • HRSA/DoT 9/2014-10/2015
9/2008-8/2014	AABB Transfusion Transmitted Diseases Committee
2006-8/2014	PHS Blood Emerging Infectious Diseases Working Group

Cross-representational

10/2016-2/2018	HRSA Representative to the HHS Blood, Organ and Tissue Senior Executive Council
5/2015-2/2018	HRSA Ex Officio Member of the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA)
3/2014-5/2015	HRSA Alternate Ex Officio Member to ACBTSA
3/2013-10/2014	Informed Consent Subcommittee of the HHS Advisory Committee on Blood and Tissue Safety and Availability
11/2011-Present	World Health Organization's Project Notify Editorial Board
11/2010-3/2011	Contributor to World Health Organization's Project Notify Member: Group 2 (Tissues), Group 6 (Infectious Diseases)
12/14-15/2009	Scientific Committee for Workshop: Emerging Arboviruses: Evaluating the Threat to Transfusion and Transplantation Safety
8/2006-8/2014	FDA Liaison to American Association of Tissue Banks 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

Other

11/2002-3/2010	FDA Research Involving Human Subjects Committee (FDA's IRB); CBER Member
6/28/2007	USPHS Medical Review Board
9/2004-8/2014	CBER Tissue Safety Team
10/2001-3/2010	CBER Commissioned Corps Awards Review Committee
10/2003-2005	OCTGT alternate representative to CBER Counter Terrorism Coordinating Council (CTCC)

USPHS ASSIGNMENTS

07/2016-2/2018	Director, Division of Transplantation (DoT), Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HSB)

Duties: Leads Division of Transplantation, which has oversight responsibilities for multiple national public health programs related to organ and blood stem cell transplantation in the United States—including the Organ Procurement and Transplantation Network (OPTN), Scientific Registry for Transplant Recipients (SRTR), CW Bill Young Transplantation Program (CWBYTP), Stem Cell Therapeutics Database (SCTOD), National Cord Blood Inventory (NCBI), the National Living Donor Assistance Center (NLDAC), public outreach contracts, and grant activities. HRSA spokesperson for the organ transplantation and blood stem cell transplantation programs. Develop and manage relationships with diverse national-level stakeholder groups, including government and non-government, to further the mission of DoT programs. Provide policy and program oversight in close collaboration with HRSA leadership.

FY 2017 Program Accomplishments

- Leads national programs with FY 2017 spending of $23.5 million for organ transplantation, and $34.375 million for blood stem cell transplantation
- Implemented the first year of the OPTN Collaborative Innovation and Improvement Network (COIIN) model, with an eye toward transforming transplant system performance evaluation. The aim of this COIIN is to increase the use of harder-to-place donor kidneys while improving process and maintaining good outcomes, hoping to ultimately increase the overall number of kidneys transplanted—the best outcome for individuals in need of a transplant.
- Successfully re-competed and awarded new contracts for the CWBYCTP.
- In 2016 organ transplantation programs had 5th year of record-high number of organs transplanted—33,600 total transplants achieved representing an 8.5 % increase over 2015 total and increase of 19.8% since 2012.
- Supporting living donation to increase the availability of organs for transplant by initiating the SRTR in developing a pilot living donor outcomes registry, and an SRTR report on the design of a pilot project to fund lost wages for living donors.

- Initiated a study on Zika testing of organ donors – the first IND study testing the effectiveness of donor screening tests for use in organ donors for an emerging infectious disease.
- Office of the Assistant Secretary for Health, in collaboration with HRSA, contracted RAND study "Challenges to the Sustainability of the U.S. Public Cord Blood System" published September 2017.
- HRSA co-sponsored National Academies of Science, Engineering and Medicine study "Opportunities for Organ Donor Intervention Research: Saving Lives by Improving the Quality and Quantity of Organs for Transplantation" published October 2017.

FY 2016 Program Accomplishments

- DoT strengthened stakeholder collaboration through multiple initiatives, including the White House Organ Summit (6/2016), Living Donor Coalition (first planning meeting 12/2016), Innovation in Transplantation Workshop (10/2016), monthly communication coordination meetings with Donate Life America and United Network for Organ Sharing, Office of the Assistant Secretary of Health sponsored study of cord blood industry finances (as recommended by ACBSCT), collaborative planning with CMS to increase kidney availability, co-sponsorship of Institute of Medicine Study on donor intervention research, Zika research co-sponsored with FDA and NIAID, and Zika research is planned for 2017 that is funded by CDC through IAA with HRSA.
- A proposed rule and a final rule were written and HRSA-cleared.
- Division work products meet deadlines with improved quality over FY 2015.
- An appropriations report and four congressional reports were written and successfully cleared.
- Successful Division reorganization (FY 2016) with resultant improved efficiency, employee satisfaction, and workplace engagement.

10/2015-07/2016 Acting Director, DoT, HSB, HRSA

Duties: Leads Division of Transplantation, which has oversight responsibilities for multiple national public health programs related to organ and blood stem cell transplantation in the United States—including the Organ Procurement and Transplantation Network (OPTN), Scientific Registry for Transplant Recipients (SRTR), CW Bill Young Cell Transplantation Program (CWBYCTP), Stem Cell Therapeutics Outcomes Database (SCTOD), the National Living Donor Assistance Program (NLDAC), outreach contracts, and grant activities. HRSA spokesperson for the organ transplantation and blood stem cell transplantation programs. Develop and manage relationships with diverse national-level stakeholder groups, including government and non-government, in order to further the mission of DoT programs, providing policy and program oversight.

Accomplishments: Developed and implemented reorganization plan to improve the efficient and effective operation of the Division in providing its oversight of national programs. The Division performance in planning for budget and contract cycles is improved, with work more coordinated between DoT and the Bureau and other parts of HRSA. Leaders within DoT are guiding their staff in providing higher quality oversight of their programs and contracts and are providing higher quality work products (including reports to congress, appropriations reports, policy documents, decision memos) in a timely manner. Managing Zika-virus public health emergency issues for products involving DoT programs, including guiding OPTN information guidance through HHS clearance, reviewing and advising on national messaging, and coordinating efforts with other HHS Agencies. Two major policy initiatives for the Division (involving paired organ donation and amending Section 301 of the National Organ Transplant Act to preclude payment to donors of stem cells collected by apheresis) were successfully HRSA-approved for rulemaking in the 2016 calendar year.

8/2014-9/2015 Medical Officer, DoT, HSB, HRSA

Duties: Advises DoT Director on organ and blood stem cell programs and policy development, including in areas of program management, medicine, managing stakeholder relationships to and outreach grant program administration. Provides monitoring and oversight of OPTN and CWBYCTP program activities. Provides advice and guidance to leadership (HRSA, other parts of government, national stakeholders) regarding DoT's national public health programs. Serves as a liaison to multiple stakeholder groups, including government, contractors, and the transplant community. Serve as subject matter expertise in organ and blood stem cell transplantation issues. Leads and contributes to multiple policy initiatives in organ and blood stem cell transplantation. HRSA leader for donor intervention research efforts within the organ transplant community.

Accomplishments: In a brief timeframe has developed extensive knowledgeable of DoT's policies and procedures and transplantation policy and issues as an integrated member of the DoT team. As a result of analysis of the effectiveness of monitoring of OPTN activities, developed a strategy for determining how to address the need to improve data collection and use within the transplantation system. Written and contributed to the writing of numerous documents, including those in the areas of policy, regulation development, stakeholder inquiry response, and congressional inquiry responses. Developed working knowledge of the budgets and program requirements of all DoT programs (including contracts, grants, and a cooperative agreement) in order to contribute to oversight and monitoring of those programs.

3/2010-8/2014 Chief, Human Tissue and Reproduction Branch, Division of Human Tissues (DHT), Office of Cellular, Tissue and Gene Therapies (OCTGT), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA)

Duties: Envision, plan and implement broad policy and national programmatic initiatives. Maintain knowledge and situational awareness of major policy issues and stakeholder concerns within the tissue, cell, blood and organ communities through meetings, stakeholder contact, committees and consultation. Work directly with Office of Blood Research and Review (OBRR) and HHS Agencies on cross-cutting policy initiatives, developing common solutions to public health needs consistent with Office or Agency missions. Manage, supervise and mentor all division staff and fellows as the branch chief in a division with only one branch. Serve as review authority for written correspondence, presentations and communication strategies. Ensure compliance of regulated industry with FDA regulatory programs by reviewing reports, regulatory submissions, operating procedures, and other documents to identify deficiencies and recommend solutions.

Accomplishments: Nationally and internationally recognized authority and subject matter expert in donor screening and testing and regulatory review, with vision for public health needs in research and policy development. Developed and implemented significant national programmatic and policy initiatives while hiring, mentoring, and training a staff that more than doubled in size over the first year.

- Recognized the growing gap in knowledge and data to inform policy decisions for cell and tissue safety compared to data underlying blood safety decisions; developed and implemented a strategy to focus policy efforts and research needs for transplant safety through a series of initiatives.
    - Identified need for broadening review policy for evaluating infectious disease assays for use in organ transplantation. Led multi-year initiative across multiple HHS Agencies and with public and private stakeholder groups culminating in the 5 December 2012 Blood Products Advisory Committee meeting discussing the scientific data most important to the organ transplant community that FDA could use in evaluating assay performance. Supervised and mentored FDA staff in all aspects of coordinating the multi-Agency and multi-Center committee planning the topic for the Advisory Committee discussion.
    - Collaborated with OBRR in developing Food and Drug Administration's Emerging Infectious Diseases Workshop held 5/11-12/2010; negotiated and led a separate day to discuss tissues and organs in a manner distinct from, but coordinated with, blood-related discussions in order to discuss developing a broad research agenda to advance science related to donation of cells, tissues and organs (Summary document submitted for publication).
    - Initiated and lead OCTGT Emerging Infectious Diseases Working Group whose mission is developing new policy initiatives for donor screening and testing, systematic approaches to evaluating emerging infectious diseases, improving the collection and review of national public health data, and advising on related OCTGT policy approaches.
    - Developed and initiated research studies for data collection to improve knowledge of clinical performance of infectious disease tests with cadaveric specimens.

- Contributed leadership and subject matter expertise to several multidisciplinary and multi-Agency policy initiatives
    - OCTGT lead to FDA Multi-Center Working Group determining FDA policy position for banked human milk
    - MSM Working Group of the Office of the Assistant Secretary for Health
    - Advisory Committee (AC) planning and presentations including AC on Blood and Tissue Safety and Availability (ACBTSA), Blood Products AC, Transmissible Spongiform Encephalopathies AC, Pediatric AC
    - FDA reviewer of multiple HHS-wide documents including Draft PHS Guidelines for Organ Transplantation, Hepatitis B Action Plan, Vascular Composite Allograft proposed rule, Blood Vessels Recovered with Organs and Intended for Use in Organ Transplantation
    - 2nd [Organ] Donor-Derived Consensus Conference to evaluate the testing of solid organ donors to prevent the transmission of West Nile Virus
- Examples of programmatic duties and accomplishments include
    - Supervisory: Responsible for distribution of work assignments for DHT staff
    - Contracting: Worked with FDA contracting office to develop a contract; supervised one full-time and one part-time contract employee (on-site) for a one year special project; Member of HHS working group providing oversight of a contract administered by the Office of the Assistant Secretary for Health for the Tissue and Organ Donor Epidemiology Study
    - Budget: Assisted with Division of Human Tissues yearly budget development process and provided oversight of the budget through the course of the year to ensure compliance
    - Employee Performance: Developed yearly performance plans for the Division staff, provided performance feedback on biweekly basis as well as formal feedback via PMAP and commissioned corps evaluation processes, managed employee conflict situations
    - Hiring: Wrote all recruitment ads, USA Jobs postings, position descriptions, and all other technical aspects of recruitment and hiring for all staff hired within the Division of Human Tissues
    - Programmatic: Developed and implemented plan for records management for the Division's many paper and electronic records in preparation for a move to another campus and the simultaneous restructuring of FDA records management requirements; Oversight of performance metric reporting for the Human Cell and Tissue Registration database by the Human Tissue Registration Coordinator
    - Training: 12/2012-10/2013 American Society for Quality Certified Manager of Quality/Organizational Excellence; 10/28/2011 Certificate of Completion: CBER's Supervisor and Management Program (see course listings in Public Health Training section); responsible for planning and implementing staff development by providing mentoring and ensuring staff were provided formal training opportunities

11/2011-2/2011 Associate Public Health Advisor for Blood, Organ and Tissue Safety (Detail Assignment)
Office of the Assistant Secretary for Health (OASH)
Blood Safety and Availability (BSA)

Duties: Provide intellectual leadership for complex policy and program issues within Blood Safety. Contribute to the Departmental goals of enhancing blood safety and availability through strategies to determine the safety of blood donation from men who have had sex with men (MSM). Lead planning and preparation activities of the Advisory Committee on Blood Safety and Availability (ACBSA, now ACBTSA), including evaluation of both short- and long-term needs. Facilitate collaboration among Department of Health and Human Services (HHS) Agencies on policy issues related to the safety of blood, organs and tissues.

Accomplishments: Provided leadership and subject matter expertise in Blood Safety and Availability/OASH for broad policy issues, advisory committees, and research strategy during a period of leadership transition, both within Blood Safety and Availability and reporting authority within HHS.

- Leader in planning and organizing all ACBSA-related activities. Developed agenda, identified speakers and invited speakers, prepared opening summary materials for Assistant Secretary for Health (ASH) for the December 2011 meeting. Devised strategy to coordinate HHS follow-up on ACBSA recommendations. Prepared correspondence to/from ACBSA Chair/ASH, prepared and delivered briefing materials to ASH, prepared briefing materials for Blood Organ and Tissue Senior Executive Council (BOTSEC).
- Leading development of June 2012 ACBSA meeting, including topic development, draft Federal Register Notice, draft agenda.
- Reviewed ACBSA charter and current Committee needs. Solicited submission of nominations from candidates filling needed roles on ACBSA, prepared recommendations for ACBSA Committee Member selection.
- Developed research strategy for the Organ and Tissue Donor Epidemiology Study, coordinated feedback and buy-in for project from NIH, FDA, CDC and HRSA, prepared funding application for 2012 Program Evaluation Funds, presented project to funding review committee.
- Support MSM Working group in developing HHS plan to perform research necessary to evaluate blood donation policies for MSM—provided regulatory expertise to BSA, review and edit Request for Information, and meeting agendas.
- Provided subject matter expertise and leadership in broad policy areas including the FDA blood regulations, draft PHS Guidelines for organ donor evaluation, transplant tourism, and tissue, organ and blood donor testing.

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

Duties: Developed broad ranging subject matter expertise in multiple areas, including infectious diseases, emerging infectious diseases, donor evaluation, infectious disease

testing, regulatory device review, blood policy, review and surveillance of adverse events, and the mission, organization, and major programs of HHS Agencies. Collaborated extensively with the Office of Blood to develop and coordinate all donor-related policies. Developed and maintained relationships serving as a liaison with multiple external stakeholders including industry sponsors, industry organizations, professional societies, industry leaders, other FDA Offices and Centers, HHS Agencies and OASH. Communicated complex FDA policy and program information to stakeholders, FDA staff, and HHS Agencies. Communication included speeches at public meetings, briefings, guidance documents, peer-reviewed publication, Advisory Committee discussions, response letters congressional and stakeholder inquiries, and other inter-Agency communication. Regulatory review to ensure that designs were scientifically sound, and conformed with Federal standards and FDA regulations.

Selected Accomplishments: Became recognized leader, trusted partner, and preferred speaker for donor screening and testing and regulatory review issues within regulated industry, professional organizations, and HHS. Leader in developing all donor screening and testing policy within OCTGT, beginning during the finalization of human cell and tissue rulemaking, and at all times since.

- Led planning, development and writing of all donor screening and testing regulatory guidance and policy documents and web materials from OCTGT since its inception.
- Developed, in collaboration with OBRR, the approach to regulatory review of donor screening claims for donors of human tissues, human cells, other living donors, and organ donors. Wrote and published guidance for obtaining an indication for use in testing cadaveric specimens for donor screening purposes. Trained all FDA staff who currently perform such review work.
- Leader in developing content/agenda and planning for numerous advisory committee meetings and public workshops.
- Recognized the need for improved process for reviewing and managing adverse event information in a timely manner, and the need for improved coordination with CDC and HRSA for cross-cutting issues following communicable disease transmission events and criminal activities related to the procurement of human tissues. Influenced the development of the Tissue Safety Team that served as a model for CBER in developing safety teams for subsequent product areas. Leader in developing model for official communications with CDC for adverse event investigations. Leader in developing regular communication activities with OBRR, CDC and HRSA. 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 formation of the Office of Cellular, Tissues and Gene Therapies.

- Collaborated in the review comments to human tissue rules and develop responses and commensurate rule changes. Participated in all levels of Agency and HHS discussions and communications with respect to finalizing the rules during a period of transition of administrations between the proposed and final rulemaking.
- Collaborated with subject matter experts in OBRR in developing and writing guidance for how to screen cell and tissue donors for TSEs. In response to concerns for public health threats posed by TSEs to the safety of tissue transplantation, the guidance was published in advance of finalized rulemaking that would have provided the authority to require donors to be evaluated for TSEs.

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: Helped CBER communicate complex policy issues in response to external stakeholders, congressional inquiries, and to other HHS Agencies.
Accomplishments: Developed thorough working knowledge of all CBER-regulated products—blood, tissues, cells, vaccines, therapeutic products—as well as communication strategies and the Freedom of Information Act. Became valued team member with expertise in all forms of communications provided through the Office, and provided medical expertise to communications previously lacking that insight.

- In response to urgent issues such as product shortages, product recalls, and illegal claims made for products that should have been under CBER oversight, was primary author of numerous Q&A response documents for use as Center-wide communications.
- Led development of CBER program for outreach to healthcare providers.

OTHER PROFESSIONAL EXPERIENCE AND OUTSIDE ACTIVITIES

3/31/2018	Retirement from USPHS
7/2006-12/2012	USPHS Rapid Deployment Force (RDF) Team-2
1/2010-12/2012	Deputy Commander/Chief Medical Officer, RDF-2
8/13/2010	PHS Recruitment event at East Tennessee State University
4/1/09-1/2010	Director, Medical Services Branch RDF-2
2006-3/31/2009	Team Leader, Team Health Section RDF-2
2000-2010	Instructor of Pathology, Uniformed Services University of the Health Sciences
5/2001-8/2011	Internal Medicine Staff, Walter Reed Army Medical Center, Washington, DC
7/2000-7/2002	Internal Medicine Staff, National Naval Medical Center, Bethesda, Maryland
6/1987-9/1988	Laboratory technologist, Galbraith Laboratories, 2323 Sycamore Dr., Knoxville TN 37921

PUBLICATIONS
Peer-Reviewed

Greenwald MA, Namin S, Zajdowicz J, Jones AL., Fritts L, Kuehnert MJ, Miller CJ, and Ray G. Testing of Tissue Specimens Obtained from SARS-CoV-2 Nasopharyngeal Swab-Positive Donors. Cell and Tissue Banking, 2023. DOI 10.1007/s10561-023-10119-8

Greenwald MA, Grebe E, Green V, Jones AL, Linnen JM, Williamson P, Busch MP, Kuehnert MJ. Low rate of detection of SARS-CoV-2 RNA in deceased tissue donors. Cell Tissue Bank. 2022 Dec 9:1–12. doi: 10.1007/s10561-022-10054-0. Epub ahead of print. PMID: 36484950; PMCID: PMC9734833.

Theodoropoulos NM, **Greenwald MA**, Chin-Hong P and Ison M.G. Testing deceased organ donors for infections: An organ procurement organization survey. American Journal of Transplantation. 2021; 21:1924-1930. https://doi.org/10.1111/ajt.16552

Contributors to the C4 Article. Current Opinions in Organ Allocation. American Journal of Transplantation. 2018;18:2625-2634. DOI: 10.1111/ajt.15094

Fishman JA, **Greenwald MA**. Innovation in Organ Transplantation: A Meeting Report. American Journal of Transplantation. 2018;00:1–4. DOI: 10.1111/ajt.14928

Greenwald MA. Shifting the Conversation on Outcomes Reporting. American Journal of Transplantation. 2018;18:1303–1304.DOI: 10.1111/ajt.14735

Greenwald MA, Kerby S, Francis K, Noller AC, Gormley WT, Biswas R, and Forshee RA. Detection of Human Immunodeficiency Virus, Hepatitis C Virus, and Hepatitis B Virus in Post-mortem Blood Specimens Using Infectious Disease Assays Licensed for Deceased-Donor Screening. Transplant Infectious Disease. Online January 19, 2018. DOI: 10.1111/tid.12825

Hashmi SK, Bredeson C, Duarte RF, Farnia S, Ferrey S, Fitzhugh C, Flowers MED, Gajewski J, Gastineau D, **Greenwald MA**, Jagasia M, Martin P, J. Rizzo D, Schmit-Pokorny K, Majhail NS. National Institutes of Health Blood and Marrow Transplant Late Effects Initiative: The Healthcare Delivery Working Group Report. Biol Blood Marrow Transplant 23 (2017) 717–725. http://dx.doi.org/10.1016/j.bbmt.2016.09.025

Cortez KJ, **Greenwald MA**. Current Trends in Donor Testing to Detect Syphilis Infection. Current Infectious Disease Reports. September 2014; 16(9): 423. PMID: 25048112

Greenwald MA, Kuehnert MJ, Fishman JA. Addressing the Threat of Emerging Infectious Disease Transmission Through Organ and Tissue Transplantation. Emerging Infectious Diseases, [serial on the Internet]. August 2012; 18(8).

Fishman JA, **Greenwald MA**, Grossi PA. Transmission of Infection with Human Allografts: Essential Considerations in the Development of Donor Screening Programs. Clinical Infectious Diseases. 1 September, 2012; 55: 720-727. PMID: 22670038

Fishman, JA; **Greenwald, MA**; Kuehnert, MJ. Enhancing Transplant Safety: A New Era in the Microbiologic Evaluation of Organ Donors? American Journal of Transplantation. Dec 2007; 7: 2652-2654. PMID: 17983389

Lee, EH; Ferguson, D; Jernigan, D; **Greenwald, MA**; Coté, T; Bos, JE; Guarner, J; Zaki, S; Schuchat, A; Beall, B; Srinivasan, A. Invasive Group-A Streptococcal Infection in an Allograft Recipient. The Journal of Bone and Joint Surgery. September 2007; 89:2044-7. PMID: 17768205

CDC. Invasive *Streptococcus pyogenes* After Allograft Implantation --- Colorado, 2003. Morbidity and Mortality Weekly Report. 2003; 52:1173-1176. Reported by: J Bos MPH, JM Crutcher MD, K Gershman MD, T Coté MD, **MA Greenwald MD**, J Polder MPH, A Srinivasan MD, M Arduino DrPH, DB Jernigan MD, B Beall PhD, JA Elliott PhD, RR Facklam PhD, A Schuchat MD, C Van Beneden, E Lee MD, and D Ferguson MD. PMID: 14654764

Byrd, JC, Waselenko JD, Maneatis TJ, Murphy T, Ward FD, Monahan BP, **Sipe MA**, Donegan S, and White CA. 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

Academic

Cortez, KJ, Lazarus, E, & **Greenwald, MA** (2013). Chapter 11: FDA Regulatory Approach to Regulating Reproductive Tissues. In M.V. Sauer (ed), *Principles of Oocyte and Embryo Donation* (2nd Edition, pp. 319-335). London, England: Springer.

Garzoni C, **Greenwald M**, Kotton C, Schwartz B (2011). The Transmission of Infections: 13 Parasitic Transmissions. In NOTIFY: Exploring Vigilance Notification for Organs, Tissues and Cells—A Global Consultation (pp. 73-75). Bologna, Italy: Editrice Compositori.

Trade Press

Greenwald, MA. FDA Takes Aim at Regenerative Medicine Compliance with New Rapid Inquiry Program. Cell & Gene (online). September 19, 2019. URL: https://www.cellandgene.com/doc/fda-takes-aim-at-regenerative-medicine-compliance-with-new-rapid-inquiry-program-0001

Regulatory

The Food and Drug Administration. Draft Guidance for Industry: Use of Donor Screening Tests to Test Donors of Human Cells, Tissues and Cellular and Tissue-Based Products (HCT/Ps) for Infection with Treponema pallidum (Syphilis). 10/2013. (Co-Author—Senior Author)

The Food and Drug Administration. Draft Guidance for Industry: Use of Nucleic Acid Tests to Reduct the Risk of Transmission of West Nile Virus from Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps). 10/2013. (Co-Author—Senior Author)

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—sole OCTGT author, joint project with the Office of Blood Research and Review (OBRR))

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—sole OCTGT author, joint project with OBRR)

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).

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).

PRESENTATIONS

National

19 September 2023. Physicians Council MTB Working Group: Interim *Mycobacterium tuberculosis* (MTB) Donor Screening Requirements. At American Association of Tissue Banks Annual Meeting held 17-20 September 2023 at National Harbor, Maryland.

23 August 2023. Physicians Council MTB Working Group: Interim *Mycobacterium tuberculosis* (MTB) Donor Screening Requirements. Live Webinar [National] with Question-and-Answer Session for Eye Bank Association of America.

21 August 2023. Physicians Council MTB Working Group: Interim *Mycobacterium tuberculosis* (MTB) Donor Screening Requirements. Recorded Webinar [Posted for National audience] for American Association of Tissue Banks.

11 May 2023. FDA Regulation of Human Cells and Tissues: What Reproductive Establishments Need to Know. At 2023 American Association of Bioanalysts Conference & College of Reproductive Biology Symposium held in Las Vegas Nevada, May 9-12, 2023.

September 2022. AATB Physicians' Council Business Update (9/19). AATB Scientific and Technical Affairs Committee COVID Studies Update (9/21). Mycobacterium tuberculosis: AATB Panel on Mtb and Physicians Council Recommendations (9/21). Connecting with AATB – Physicians Council (co-presenter, 9/22). At American Association of Tissue Banks Annual Meeting held in San Antonio, TX September 19-22, 2022.

19 July 2022. Monkeypox Virus and HCT/Ps: Epidemiological, Clinical, and Donor Screening Considerations. AATB Physicians Council Meeting. Virtual meeting with national audience.

30 June 2022. AATB COVID-19 Recommendations. Accredited Tissue Bank Council Meeting. Virtual meeting with national audience.

6 April 2022. "Current Metrics of Success: The Government Frame of Reference." AST Cutting Edge of Organ Transplantation. Virtual (rescheduled from 2/17/2022 in Scottsdale, AZ)

9 June 2021. Moderator for "IMPACT Session: The Role of the US Federal Government in Solid Organ Transplantation." American Transplant Congress, Virtual Connect.

4 November 2020. “HCT/P Regulatory Pathways.” American Association of Tissue Banks, Webinar.

13 October 2020. “Tissue Donor SARS CoV-2 Testing: Study Update.” American Association of Tissue Banks Annual Meeting, Virtual.

23 June 2020. “Donor Testing During COVID-19: Current Technical Aspects of Testing.” Association of Organ Procurement Organizations Annual Meeting, Virtual.

11 May 2020. “Donor Testing – What will be the Standard Moving Forward.” American Society of Transplantation Town Hall Meeting held via Zoom Conference to an international audience.

17 October 2019. “Reimbursement of Organ Procurement Organizations” (and panel moderator) at Advanced Regenerative Manufacturing Institute Fall Summit held October 16-17 in Manchester, NH.

26 September 2019. “So they said Yes on the DRAI, now what do I do?” At American Association of Tissue Banks held 24-27 September 2018 in Toronto, ON, Canada.

20 May 2019. “Innovation in Organ Transplantation Meeting Report.” At Advisory Committee on Organ Transplantation (ACOT) [virtual] meeting held 20 May 2019.

25 September 2018. “The US Transplant System: Building to the Future.” At Region 9 Organ Donation and Transplantation Collaborative meeting held 25 September 2018 in Rochester NY.

5 June 2018. “National Oversight of Donor (Intervention) Research: How Can This be Provided?” At American Transplant Congress held 2-6 June 2018 in Seattle WA.

9 February 2018. “HRSA Role as a Force for Innovation in Transplantation.” At AST Cutting Edge of Transplantation held 8-10 February 2018 in Phoenix AZ.

9 February 2018. “The Future – What Would an Ideal Report Card Look Like?” At AST Cutting Edge of Transplantation held 8-10 February 2018 in Phoenix AZ.

12 January 2018. “Opportunities for Innovation in Organ Transplantation.” At American Society of Transplant Surgeons (ASTS) Winter Symposium held 11-14 January 2018 in Miami, FL.

12 January 2018. Panelist in “Group Perspectives Discussion Q&A.” At ASTS Winter Symposium held 11-14 January 2018 in Miami, FL.

12 January 2018. “The Future of Metrics: Perspectives from UNOS and HRSA.” At ASTS Winter Symposium held 11-14 January 2018 in Miami, FL.

12 January 2018. Panelist in "Saving More Lives—What's the Right Metric?" At ASTS Winter Symposium held 11-14 January 2018 in Miami, FL.

19 September 2017. "HRSA Perspective on Transplantation Including VCA." At Evolving Issues of Vascularized Composite Allo-transplantation symposium held 19 September 2017 in Baltimore MD.

13 November 2016. Panel Participant in "Challenges and Lessons Learned from Influencing National Policy Change in Organ Transplant." At Institute for Operations Research and the Management Sciences Annual Meeting 2016 held 12-16 November 2016 in Nashville TN.

4 November 2016. "HRSA and VCA: Moving from Experimentation to Standard of Care." At American Society for Reconstructive Transplantation 5th Biennial Meeting held 3-5 November 2016 in Chicago IL.

16 September 2016. Panel participant in "Closing the Organ Donation Gap: A Second Chance at Life." Sponsored by Congresswoman Donna Edwards. At 46th Congressional Black Caucus Foundation Annual Legislative Congress held 14-18 September 2016 in Washington DC.

17 June 2012. "Donor Testing: FDA Perspectives" in Controversies in Transplantation Microbiology. At American Society for Microbiology, San Francisco CA held 16-19 June 2012.

5 June 2012. Invited moderator for Sunrise Symposium: Donor Screening for Infection: New Guidelines and the Transplant Community. At American Transplant Congress, Boston MA held 3-6 June 2012.

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.

3 November 2008. "Update: Infectious Disease Issues for HCT/Ps." American Academy of Orthopedic Surgeons Device Forum in Bethesda, MD.

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.

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

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.

International

19 October 2023. Session: We have no lack of potential Donors, we have a lack of Organization - Overview of international Tissue Donation and Banking Systems. "Tissue Donation in USA" and "Tissue Donation - International Perspectives" panel discussion. At ISODP 2023 (International Society for Organ Donation and Procurement) in Las Vegas, Nevada held 18-21 October 2023.

20 June 2022. "The US experience with COVID-19 positive donors." At WHO Project Notify Technical Meeting in Rome, Italy held 20-21 June 2022.

17 May 2019. "Laboratory Services for Pre- and Post-Transplant Testing." At Organ Donation Innovative Strategies for Southeast Asia (ODISSeA) Train the Trainer meeting in Barcelona, Spain held 13-17 May 2019.

30 November 2011. "View from USA." Pan American Health Organization's Surveillance for Transparency in Transplantation in the Americas in Buenos Aires, Argentina.

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 Bukittinggi, West Sumatra, Indonesia held 27-30 October 2010.

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.

Advisory Committee

22 November 2016. "Organ Transplantation Program Update." At Advisory Committee on Organ Transplantation. Virtual meeting held 22 November 2016.

13 September 2016. "Blood Stem Cell Transplantation Program Update." At Advisory Committee on Blood Stem Cell Transplantation. Meeting held 13-14 September 2016.

17 November 2015. "Organ Transplantation Program Update. At Advisory Committee on Organ Transplantation. Virtual meeting held 17 November 2015.

7 April 2015. "ACOT Update." At Advisory Committee on Blood and Tissue Safety and Availability 46th Meeting in Rockville, MD held 7-8 April 2015.

1 August 2011. "U.S. vCJD Donor Screening: Human Cells, Tissues and Cellular and Tissue-Based Products." At Transmissible Spongiform Encelphalopathies Advisory Committee in Gaithersburg, MD.

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

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.

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.

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.

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.

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.

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.

Workshops

Organizer

8-10 June 2017. "Cord Blood Clamping: Timing and Impact" workshop held at the International Cord Blood Symposium. Held in San Diego, CA.

20-21 October 2016. "Research Innovation in Organ Transplantation." Co-organizer with Jay Fishman. Held in Rockville, MD.

11-12 May 2010. FDA Emerging Infectious Diseases Workshop. Organizer of HCT/P session on 12 May. Held in Gaithersburg, MD.

Invited

30-31 January 2017. "AST HCV Consensus Meeting." Held in Dallas, TX.

15 January 2011. "Available Relevant Medical Records." At American Association of Tissue Banks Donor Suitability Workshop V in McLean, VA held 15-17 January 2011.

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.

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.

8 March 2010. "Donor Eligibility for Cord Blood Donors: Selected Topics." At Cord Blood Licensure: A Workshop, AABB-sponsored, in Rockville, MD held 8-9 March 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.

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.

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 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."

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.

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.

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.

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.

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.

Industry/Constituent Meetings

21 November 2023. "AATB and US Tissue Banking System." Veterans Health Administration Pathology and Laboratory Medicine Services (VHA P&LMS) Monthly Call.

14 September 2023. "34 Lives: Normothermic Machine Preservation." At Donor Alliance Research Day held 14 September 2023 in Denver, CO.

24 March 2014. "FDA HCT/P Regulatory Update." Pharma Conference in Bethesda, MD held 24-26 March 2014.

14 January 2014. "The Medical History Interview for HCT/P Donors." American Association of Tissue Banks Donor Risk Assessment Interview (DRAI) Workshop in McLean, VA held 14-15 March 2014.

6 October 2011. "FDA Regulatory Framework: Validation and Verification." Eye Banking Association of America's FDA Validation Workshop in Arlington, VA.

24 June 2011. Transplant Panel Discussion. Eye Bank Association of American Annual Meeting – 50th Anniversary in Tucson, AZ held 22-26 June 2011.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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 on officer's behalf because of unavailability due to Katrina deployment.

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.

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.

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 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.

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.

Training

16 July 2013. "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 15-19 July 2013.

13 Dec 2011. "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 12-16 December 2011.

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.

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.

2 December 2009. "Human Milk Banking" to Office of Cellular Tissues and Gene Therapies.

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.

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

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.

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.

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.

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

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.

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.

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.

RESEARCH

2020-2022 Testing of Tissue Specimens Obtained from SARS-CoV-2 Naopharyngeal Swab-Positive Donors. Co-PI with Gregory Ray, Christopher Miller, Matthew Kuehnert, Linda Fritts, Alyce Linthurst Jones, Jan Zajdowicz, and Shabnam Namin. Manuscript Published 2023: Cell and Tissue Banking.

2020-2022 Detection of SARS-CoV-2 RNA in deceased tissue donor retrospective samples. Co-PI with Matthew Kuehnert (MTF Biologics, Professor of Medicine, Hackensack Meridian School of Medicine at Seton Hall). Specimen collection, testing, and analysis completed; manuscript published 12/2022 in Cell and Tissue Banking.

2019-2020 Deceased Donor Screening OPO Survey. Co-PI with Nicole Theodoropoulos (Division of Infectious Diseases & Immunology, University of Massachusetts Medical School), Peter Chin-Hong (Division of Infectious Diseases, University of California San Francisco) and Michael Ison (Divisions of Infectious Diseases & Organ Transplantation, Northwestern University Feinberg School of Medicine). Study completed. Manuscript completed and accepted by American Journal of Transplantation 12/2020; manuscript published 2021.

2012-2016 Tissue and Organ Donor Epidemiology Study (advisor on HHS working group to the contractor performing the study; obtained funding through the US Department of Health and Human Services; contract awarded September 2012); Study report by contractor provided to HHS 9/2016; Manuscript preparation in progress (had been delayed because our FDA-led Working Group was on hold due to COVID).

2009-2010 Sensitivity of donor screening tests on in vivo specimens obtained from post-asystole donors. PI; data collection completed 2013, data analysis completed 2014; manuscript published 2018 in Transplant Infectious Disease.

PROFESSIONAL ORGANIZATIONS

2019-2022	American Association of Tissue Banks Physicians Council Standards Committee
2012-Present	The Transplantation Society
2010-Present	American Society of Transplantation (AST) AST Infectious Disease Community of Practice (ID COP)
2010-2016	Organ Donation Research Consortium
2007-Present	The Association of Military Surgeons of the United States
2002-3/2018	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, 1994-97

AD HOC PEER REVIEWER

American Journal of Transplantation
Journal of Clinical Virology
Xenotransplantation
Cell and Tissue Banking
Epidemiology and Infection

ACADEMIC APPOINTMENTS

2018-Present	Adjunct Associate Professor of Medicine Uniformed Services University of the Health Sciences School of Medicine
2002-2017	Adjunct Assistant Professor of Medicine Uniformed Services University of the Health Sciences School of Medicine

LICENSE/SUPPLEMENT APROVALS (as OCTGT Lead Scientific Reviewer)

For all tests reviews performed jointly with OBRR as the tests have (primary) indications for use in testing blood donors; led development of policy and language related to organ donor testing included in instructions for use (organ donor testing indication for use is included for all tests licensed for blood donors since 2003)

- 23 July 2015 BioPlex 2200 HIV Ag-AB Assay (PMA, organ donor testing claim) – note role ended with departure from FDA 8/2014
- 25 May 2012 Procleix Ultrio Plus Assay (efficacy supplement, cadaveric, organ and living donor claims)
- 26 March 2012 Avioq HTLV I/II Microelisa System (organ and living donor claim)
- 4/30/2010 Abbott PRISM Chagas (cadaveric, organ and living donor claims)
- 10/22/2009 Cobas TaqScreen West Nile Virus Test (cadaveric claim)
- 9/18/2009 Abbott PRISM HIV O Plus (cadaveric, organ and living donor claims)
- 8/27/2009 Roche MPX BLA 27 (organ and 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 (organ and 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)

NON-PHS AWARDS

10/4/2017	American Association of Tissue Bank's George W. Hyatt Award given annually to an outstanding individual scientist who has demonstrated superior research, teaching, and service abilities in the field(s) of tissue banking, tissue transplantation, or transplantation medicine
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	HHS Secretary's Award for Distinguished Service as member of the "Tissue Action Plan Team"
7/21/2004	HHS Secretary's Award for Distinguished Service as member of the "West Nile Virus Blood Screening Group"
1/2004	Navy Meritorious Unit Commendation

PHS AWARDS

2018	Distinguished Service Medal for "in recognition of her exemplary career and dedication to performance that clearly went beyond meritorious requirements while assigned to the Department of Health and Human Services (HHS)"
1/15/2014	Unit Commendation for "Planning and executing an Advisory Committee meeting on scientific and technical considerations to infectious diseases used to screen organ donors"
1/9/2013	Unit Commendation for "Leadership in working corroboratively with the Office of Commissioned Corps Operation (OCCO) Billet Transformation staff to update and individualize the billet system"
2013	Nominated for **Meritorious Service Medal**
08/16/2011	**Commendation Medal** for "Exceptional service as PHS 2 Acting Team Commander during Operation Nexus, Unicoi County, TN"
01/29/2010	PHS Special Assignment Award
12/23/2009	Unit Commendation for "Outstanding care for Gustav evacuees and providing proof of concept for PHS teams standing up federal medical stations"
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