

Rank NamePHS #, Medical Officer, CV cover sheet, DatePROFESSIONAL QUALIFICATIONS

8/97-7/99 Senior Staff Fellow, National Institutes of Health (NIH), Dept. of Transfusion Medicine
 7/1995 Board certified in Blood Banking/Transfusion Medicine, American Board of Pathology
 11/1993 Board certified in Anatomic and Clinical Pathology, American Board of Pathology
 6/1990 Armed Forces Combat Casualty Care Course, Fort Sam Houston, San Antonio, TX
 12/1989 Medical license, [redacted state], [# redacted], expiration
 7/89-5/93 Anatomic and Clinical Pathology Residency, Walter Reed Army Medical Center (WRAMC)
 7/88-6/89 Transitional Medical Internship, WRAMC, Washington, DC
 6/85-7/85 Army Medical Department Officer Basic Course, Fort Sam Houston, San Antonio, TX
 8/84-5/88 Medical Doctorate (MD), Temple University School of Medicine, Philadelphia, PA
 9/80-5/84 Bachelor of Arts (BA), Honors in Biology, Bryn Mawr College, Bryn Mawr, PA

PERFORMANCE: Team leader for regulatory submissions and health hazard evaluations; expert and consultant to scientists within FDA and other agencies for new cell/tissue regulations; team leader for development and publication of scientific review guidelines and regulatory policy for hematopoietic stem cell products; FDA representative to national and international organizations of health care providers; scientific publications in journals and textbooks

CAREER PROGRESSION AND POTENTIAL

2007 Currently serve as Director Regulatory Review Officer, Division of [Redacted], Office of Cells, Tissues and Gene Therapies, CBER, FDA: **Team leader** for over 50 currently active cell product and device applications review committees. Chair, Hematopoietic Stem Cell Committee, responsible for policy development; drafting rules, guidance and other regulatory documents for publication in the Federal Register; draft cord blood guidance published 2007; coordinator for Advisory Committee meeting on cord blood 3/07.

Recent Appointment: Ex Officio FDA Representative to the Advisory Counsel for Blood and Stem Cell Transplantation (advises HRSA on management of National Cord Blood Inventory).

Clinical Billet: Attending Staff, NIH, Dept of Transfusion Medicine

7/2008 Promotion to permanent O-6
 12/2004 Promotion to permanent O-5
 4/2003 Change of billet to Director Regulatory Review Officer (O-6 billet),
 10/2002 Change of billet to Reviewing Medical Officer, Office of Cellular, Tissue, and Gene Therapies; review responsibilities change from blood products to human cells and tissues
 7/1999 Promoted to O-5 and assigned as Reviewing Medical Officer, FDA/CBER Office of Blood Research and Review, Rockville, MD
 8/1997 Call to duty as O-4 in USPHS, Senior Staff Fellow at NIH, Bethesda, MD
 7-10/1996 Assigned as Acting Chief, Clinical Pathology, William Beaumont Army Medical Center (WBAMC), El Paso, Texas
 6/1994 Promoted to O-4, US Army Reserves, WBAMC
 7/93-10/96 Assigned as Staff Pathologist and Blood Bank Medical Director, WBAMC (USAR)
 7/1989 Assigned to residency training, US Army Reserves, WRAMC
 7/1988 Assigned to first year graduate medical education, US Army Reserves, WRAMC
 6/1988 Promoted to O-3, US Army Reserves, Washington, DC
 8/1984 Commissioned as O-2 in the US Army Reserves (USAR)

PHS AWARDS

2008 – Outstanding Service Medal
 2007 – Unit Commendation, Outstanding Unit Citation, FMRB
 2006 – Crisis Response Service Award, Unit Commendation
 2005 – Unit Commendation
 2004 – Commissioned Corps Training Ribbon
 2004 – Achievement Medal
 2003 – Outstanding Unit Citation
 2002 – Achievement Medal
 2000 – PHS Citation
 1998 – Bicentennial Unit Commendation

Non-PHS AWARDS

2007 – Commissioner's Special Citation
 2005 – Secretary's Award for Distinguished Service
 1999 – AABB Fenwal Award – Transfusion Medicine
 1996 – Army Commendation Medal
 1992 – Army Superior Unit Award
 1992 – National Defense Service Medal (US Army)
 1988 – Alpha Omega Alpha Honor Medical Society
 1988 – Army Service Ribbon
 1985 – Health Professions Scholarship (Army)

READINESS AND SERVICE TO PHS COMMISSIONED CORPS

- ❖ Tier 1 team leadership role: PHS 1 RDF Administration and Finance Section Chief; physically fit (level II)
- ❖ Participant in numerous PHS Boards; active in career mentoring program

- ❖ Deployments and training: Hurricane Katrina - Gulfport MS 9-10/05 (Team Commander Nevada-1 facility); BDLS Camp Bullis, TX 7/07; numerous local deployments (most recent July 4 2008); Hurricane Ike - FMS College Station 9/6-23/08 (Admin section chief)

CURRICULUM VITAE Updated Date*Office address:**Office phone:**Email:*

EDUCATION**Degree/Year Institution**

M.D./1988 TEMPLE UNIVERSITY SCHOOL OF MEDICINE, Philadelphia, PA
B.A./1984 BRYN MAWR COLLEGE, Bryn Mawr, PA
Cum laude, Honors in Biology

POST-GRADUATE TRAINING

8/97-6/99 NATIONAL INSTITUTES OF HEALTH, Warren G. Magnuson Clinical Center,
Bethesda, MD
Senior Staff Fellow, Department of Transfusion Medicine

7/89-7/93 WALTER REED ARMY MEDICAL CENTER, Washington, DC
Pathology Residency (Anatomic and Clinical)

7/88-7/89 WALTER REED ARMY MEDICAL CENTER, Washington, DC
Transitional Internship

PROFESSIONAL EXPERIENCE

4/03-present FOOD AND DRUG ADMINISTRATION, CENTER FOR BIOLOGICS
EVALUATION AND RESEARCH, OFFICE OF CELLULAR, TISSUE, AND
GENE THERAPIES, Rockville, MD
Director Regulatory Review Officer, Division of Human Tissues (O-6 billet)

Major Duties:

- Team leader for over 50 active hematopoietic cell product and device applications, including Investigational New Drug Applications and Device Pre-market Notifications
- Medical expert and consultant to scientists within FDA and other federal agencies for new human cell/tissue regulations
- Chair, Hematopoietic Stem Cell Committee to develop scientific review guidelines and publish regulatory policy documents in the Federal Register for regulated stem cell products
- FDA representative and consultant to national and international professional organizations

- Subject matter expert in hematopoietic stem cell therapies and transfusion medicine; perform educational outreach in area of expertise by participating as lecturer and moderator at international medical symposia; author and contributor to scientific publications in peer-reviewed journals and textbooks

Major Recent Accomplishments:

- Contributed to national and international efforts to standardize labeling of cell therapy products, and to harmonize the labeling with international regulatory authority requirements, by serving as FDA liaison to professional organizations that publish labeling guidelines and accreditation standards (Circular of Information for Cell Therapy Products; ISBT 128 US Consensus Standard for the Uniform Labeling of Cellular Therapy Products)
- Invited speaker and moderator at numerous national and international industry/professional cell therapy meetings and symposia (AABB Annual and Spring Meetings, International Cord Blood Forum, Pharmaconference Human Cell and Tissue Products Annual Meeting and Timely Topics, U. Minnesota Hematopoietic Growth Factors in Donors – coauthored conference summary e-published ahead of print in Transfusion, June 19, 2008)

- 10/02-4/03 FDA CENTER FOR BIOLOGICS EVALUATION AND RESEARCH, OFFICE OF CELLULAR, TISSUE, AND GENE THERAPIES, Bethesda
Reviewing Medical Officer, Division of Human Tissues
- Medical reviewer for hematopoietic cell product and device applications, including Investigational New Drug Applications and Device Pre-market Notifications, and cell product health hazard evaluations
 - Participate in agency task groups for implementation of new human cell and tissue product regulatory approach
 - Represent the FDA at regulatory and scientific meetings
 - Write and edit scientific publications in peer-reviewed journals and textbooks
- 7/99-10/02 FDA CENTER FOR BIOLOGICS EVALUATION AND RESEARCH, OFFICE OF BLOOD RESEARCH AND REVIEW, Bethesda, MD
Reviewing Medical Officer, Division of Hematology
- Serve as Medical reviewer for blood product and related device applications, blood product health hazard evaluations and recalls
 - Represent Division of Hematology in agency task group for implementation of new human cell and tissue product regulatory approach
 - Represent the FDA at regulatory and scientific meetings
 - Write and edit scientific publications in peer-reviewed journals and textbooks
- 7/99-present WARREN G. MAGNUSON CLINICAL CENTER, NATIONAL INSTITUTES OF HEALTH, Bethesda, MD
Attending Staff Physician, Department of Transfusion Medicine

- Supervise Senior Staff Fellows providing health care to patients and transfusion medicine consultation to health care providers in the Clinical Center

7/96-10/96 WILLIAM BEAUMONT ARMY MEDICAL CENTER, El Paso, TX
Acting Chief, Clinical Pathology Services

- Provided administrative oversight and guidance to medical directors of clinical laboratories.

7/93-10/96 WILLIAM BEAUMONT ARMY MEDICAL CENTER, El Paso, TX
Staff Pathologist and Medical Director, Transfusion Medicine Service and Blood Donor Center

- Performed surgical pathology, cytology, and autopsy diagnostic services for military medical center
- Provided medical oversight expertise and consultation for all transfusion medicine and blood donor issues; directly supervised 12 blood bank, donor center, and infectious disease testing laboratory technologists
- Provided training and support to resident pathologists

4/95-10/96 TEXAS TECH HEALTH SCIENCES CENTER AT EL PASO
Assistant Professor of Pathology

- Provided training and support to resident pathologists

1/95-10/96 27th MEDICAL GROUP, CANNON AIR FORCE BASE, NM
Transfusion Medicine Consultant

- Provided medical laboratory consultation and oversight for outlying military hospital

PROFESSIONAL ACTIVITIES

Professional Boards and Licenses:

12/89 MEDICAL LICENSE, State, #, expiration Date

11/93 AMERICAN BOARD OF PATHOLOGY, Certification in
Anatomic and Clinical Pathology (indefinite)

7/95 AMERICAN BOARD OF PATHOLOGY, Certification in Transfusion Medicine
(indefinite)

Professional Organizations:

College of American Pathologists (Fellow)
AABB

USPHS Commissioned Officers Association

Journal and Textbook Publications:

Redacted. *Clinical Chemistry* 1991

Redacted. *The Journal of Rheumatology* 1993

Redacted. (eds): Hematology: Basic Principles and Practice, 3rd Ed. Churchill Livingstone, New York, 2000

Redacted. *Transfusion* 2001

Redacted. (eds): Clinical Immunology, 2nd Ed. Harcourt Publishers, London, 2001

Redacted. (eds): Hematology: Basic Principles and Practice, 4th Ed. Churchill Livingstone, New York, 2005

Abstracts:

Anti-SI^a in a 51 year old African-American female (Abstract/poster): *South Central Association of Blood Banks Annual Meeting*, Pheonix, AZ, Apr 1995

Quantitation of megakaryocyte progenitors in peripheral blood stem cell products using an assay for Megakaryocyte Colony Forming Units: *AABB Annual Meeting*, San Francisco, CA, November 1999

Adoptive immunotherapy, the Food and Drug Administration and you: a regulatory approach to donor lymphocytes. *Cytotherapy* 4:5, 449-449, 2002

Implementation of the FDA regulatory approach to cells and tissues: Focus on cord blood. *Biology of Blood and Marrow Transplantation* 10:739 (2004)

COMMITTEE APPOINTMENTS

FDA Liaison

ISBT 128 Uniform Labeling of Cell Therapy Products US Consensus Standard Advisory Group
ICCBBA, Inc.
2007-present

Abstract Grader – Scientific/Administrative Categories

AABB Selection of Abstracts Program Unit

2008 (current)

AWARDS AND HONORS

Non-PHS

2/88

Alpha Omega Alpha, Temple University School of Medicine
Medical Honor Society

9/99 AABB-Fenwal Scholarship Award for Transfusion Medicine Fellows

5/05 DHHS Secretary's Award for Distinguished Service as member of the "Tissue Action Plan Team"

/07 Commissioner's Special Citation presented to the FDA Hematopoietic Stem/Progenitor Cell Task Group

Uniformed Service

6/88 Army Service Ribbon

7/92 National Defense Service Medal
For service during Operation Desert Storm

10/96 Army Commendation Medal

1/98 USPHS Bicentennial Unit Commendation

11/00 PHS Citation
For exemplary performance of duty

3/02, 4/04 PHS Achievement Medals
For exemplary performance of duty

5/03 PHS Outstanding Unit Citation

3/04 Commissioned Officers Association

10/04 Commissioned Corps Training Ribbon

2006 Crisis Response Service Award, Unit Commendation

2007 Outstanding Unit Citation, Unit Commendation, Field Medical Readiness Badge

UNIFORMED SERVICE AND TRAINING

7/07 BASIC DISASTER LIFE SUPPORT COURSE, Camp Bullis, TX

2006 OFRD Core, Discipline, and FMRB Clinical Courses
Completed on-line

4/05 INTERAGENCY INSTITUTE FOR FEDERAL HEALTHCARE EXECUTIVES,
Washington, DC

9/04 BASIC OFFICERS TRAINING COURSE, Boston, MA

8/04 MEDICAL EFFECTS OF IONIZING RADIATION, Bethesda, MD

2/04 COMBINED HUMANITARIAN ASSISTANCE RESPONSE TRAINING
COURSE, Rockville, MD

- 9/00-current PHS BOARD MEMBER (biannual service on various Boards), OCCO, Rockville, MD
- 4/90 COMBAT CASUALTY CARE/ MASS TRAUMA COURSE, Fort Sam Houston, TX
- 6/85-7/85 ARMY MEDICAL DEPARTMENT OFFICER BASIC TRAINING COURSE, Fort Sam Houston, TX