

CURRICULUM VITAE SUMMARY
TAMMY SMITH, MD, CAPT, USPHS

PERFORMANCE

- Branch Chief, Division of XX (DX): expertly leads a branch of 14 interdisciplinary scientists, to include 3 O-6 ranked officers, to plan, manage, and direct regulatory review operations, programs, and activities in the selection, coordination, and conduct of clinical trial site inspections worldwide for all drugs considered for marketing approval by the FDA ; expert FDA presenter at various national conferences on GCP
- Exceptional COER Ratings throughout PHS career, all in O-6 billets with progressively increasing leadership responsibilities with respect to Agency mission and public health
- **Honor and Unit Awards**
 - Special Assignment Award (2010)
 - PHS Recruitment Service Award (2009)
 - PHS Commendation Medal (2008, 2005)
 - PHS Unit Commendation Medal (12/2008, 10/2008, 2005)
 - PHS Regular Corps Ribbon (2007)
 - PHS Surgeon General's Exemplary Service Medal (2004)
 - PHS Citation (2003)
 - PHS Surgeon General's Certificate of Appreciation (2003)
 - PHS Commissioned Corps Training Ribbon (2002)
 - Navy and Marine Corps Awards: Commendation Medal (2002); Meritorious Unit Commendation Medal (2003, 2002, 1995); National Defense Ribbon (2002, 1995)

EDUCATION, TRAINING, AND PROFESSIONAL DEVELOPMENT

- Allergy Fellowship, Walter Reed Army Medical Center, Wash. D.C., 1997–1999
- Residency in Internal Medicine, Naval Medical Center Portsmouth, Portsmouth, VA 1995-97
- M.D., Eastern Virginia Medical School, Norfolk, VA, 1990-1994
- B.S., Biology, University of Maryland, College Park, 1986-1989

Medical Licensure: Virginia, Active

Certification:

- American Board of Allergy & Immunology 1999, recertified 2009
- American Board of Internal Medicine 1997

Training: Numerous FDA, leadership, management courses as well as annual CME (past 3 yrs: 147.5 hrs)

CAREER PROGRESSION AND POTENTIAL

- Branch Chief, FDA: Center for Drug Evaluation and Research (CDER), Division of XX (DX, Silver Spring, MD, 2008-present (PHS O-6 billet); Acting Branch Chief, 2007 to 2008 (O-6 billet)
- Medical Officer, FDA: CDER, DSI, Rockville, MD, 2006 to 2007 (O-6 billet)
- Medical Officer, FDA: Center for Drug Evaluation and Research, Division of Pulmonary and Allergy Drug Products, Rockville and Silver Spring, MD, 2002-2006 (O-6 billet)
- Service Chief Allergy-Immunology, National Naval Medical Center (NNMC), 1999-2002 (Staff Physician, Allergy-Immunology, NNMC, 2002-present on part time basis)
- Regular Corp Assimilation 2007

PROFESSIONAL CONTRIBUTIONS TO THE PHS COMMISSIONED CORPS (OFFICERSHIP)

- Physician's PAC Chair 8/2009 to present; Vice Chair from 2007-2009; PPAC Voting Member: 2005 to present
- PHS Honor Guard, 2002-present and served as recruiter in Associate Recruiter Program 2002-2009
- Member of Medical Category Appointment Board, 2007 to present
- Served on Transformation Working Policy and Design Group 4/06-9/08 for Secretary's Transformation Plan
- Represented PHS as an Allergy/Immunology Consultant to the Office of the Attending Physician at the U.S. Capitol, a position that has previously been reserved for the Army/Navy
- Represented PHS as Science Fair Judge, at NBC Health and Fitness Expo for COA supported activity

READINESS

- Consistently meets OFRD basic readiness standards and completed all requirements for the previously defined intermediate and advanced readiness standards for CCRF/OFRD; completed the Medical Management of Chemical and Biologic Casualties Course
- Deployed for CCRF/OFRD for the World War II Veterans Memorial Dedication and Inauguration Day 2005; was slated to deploy for Katrina, but team was disbanded; volunteered for Inauguration Day 2009 participation, but not deployed
- Completed President's Challenge Active Lifestyle, Bronze, Silver, and Gold programs; ACLS and BLS certified
- Armed Forces Combat Casualty Course, Fort Sam Houston, TX, 1995

CURRICULUM VITAE

1. IDENTIFICATION

Name: **TAMMY SMITH**
Citizenship: **United States**
Rank: **CAPT, USPHS**
PHS Number:

2. CAREER OBJECTIVE: To use my specialty and subspecialty training in both Internal Medicine and Allergy/Immunology to promote the health and wellbeing of the American people

3. EDUCATION

Fellowship 1997-99	Allergy and Immunology Walter Reed Army Medical Center, Washington, D.C.
Residency 1995-97	Internal Medicine Naval Medical Center Portsmouth, Portsmouth, VA
Internship 1994-95	Internal Medicine Naval Medical Center Portsmouth, Portsmouth, VA
Medical 1990-1994	Doctor of Medicine , 21 May 1994 Eastern Virginia Medical School, Norfolk, VA
Collegiate 1986-1989	Bachelor of Science, May 1989; Major in Biology University of Maryland, College Park, MD

4. CURRENT POSITION (August 2008 to present; Acting Branch Chief October 2007 to July 2008)

PRIMARY

Branch Chief
Division of XX
Center for Drug Evaluation and Research
Food and Drug Administration
White Oak, Bldg. 51, Rm. 5358
10903 New Hampshire Ave.
Silver Spring, MD 20993
Phone

Responsibilities

- Serves as **Supervisory Medical Officer (O-6 billet) as Branch Chief** in the Division of XX
- **Supervises a team of 13-14 interdisciplinary scientists** to include **3 O-6 ranked PHS officers**, to plan, manage, and direct regulatory review operations, programs, and activities in support of the FDA's Bioresearch Monitoring Inspection Program, to **ensure the integrity of data submitted in support of marketing applications and to ensure that the rights, safety, and welfare of human research subjects are protected.**
- **Expertly leads her branch in the selection, coordination, and conduct of clinical trial site inspections worldwide for all drugs considered by the FDA for approval for use in humans, a sole functionality of her branch.**
- Reviews Prescription Drug User Fee Act (PDUFA) related Official Action Indicated (OAI) cases and recommends enforcement actions against serious violative clinical investigators, sponsors, monitors/CROs to the OAI Branch.
- **Serves as lead expert to FDA's 18 review divisions and senior management on the acceptability of data for marketing approval of drugs, a mission solely handled by this branch.**
- Interacts with the Agency's medical/ scientific reviewers to facilitate interpretation of inspectional findings and impact on approvability.
- **Provides expert guidance to government and public entities** who are developing partnerships with the Agency to effectively leverage financial and human capital resources for compliance management to ensure high quality research.

- **Currently working on innovative strategies for clinical trial oversight, to include work with a Risk Based Site Selection Model for selection of sites for inspection, real time monitoring of ongoing research, and quality system based inspections of sponsor/contract research organizations.**
- Formulates and recommends effective strategies and tactics to achieve regulatory compliance and to address complex medical/scientific issues that may affect the acceptability of clinical data submitted in support of pending applications.

Accomplishments

- As Branch Chief, served as **lead advisor to DXX's Director, and senior level medical and scientific professionals in CDER's review divisions**, regarding the medical/scientific and regulatory significance of complex inspectional findings in support of application approvals to ensure that safe and effective drugs are available to the public.
- **Significantly impacted productivity and focus on data acceptability of marketing applications** by effortlessly transitioning to lead her branch as the DSI experts for evaluating data acceptability related to PDUFA applications.
- Provided expert oversight and secondary reviews of over a 142 assignments resulting in 322 inspections; 117 clinical inspection summaries; 271 letters to include 9 Warning Letters to include a high visibility WL to J&J; and 1 NIDPOE.
- Provided **expert oversight and input on several very complex cases involving marketing applications** where critical analyses were needed to provide recommendations on data integrity, which resulted in impacting determinations of approvability. Has modified the assessment of data integrity previously limited to inspectional findings and impact to particular site, to also now include the impact on the evaluation of the whole New Drug Application.
- Played a **significant role as a member of the Technical Advisory Group in the development of a Risk-Based Site Selection Model** to more appropriately utilize finite resources to select sites for inspections related to marketing applications.
- Served as Program Lead for GCP-2 Strategic Initiatives to **develop and implement innovative strategies** to improve programmatic goals.
- **Provided lead DSI management for input in the OIG study "FDAs Oversight of Foreign Clinical Trials"** to ensure accurate representation of DSI's role in clinical oversight of foreign clinical trials.
- **Engaged in several FDA Outreach activities** to include presentations as a DXX expert on Good Clinical Practice at PRIM&R, SoCRA, CDER's New Reviewer's Workshop, and the American Academy of Allergy, Asthma, And Immunology.
- Actively engaged in educational training to include over 60 hours of CME in Allergy/Immunology, and attended Harvard's prestigious "Strategic Management of Regulatory and Enforcement Agencies" course.

SECONDARY: PROFESSIONAL DEVELOPMENT

Staff Allergist/Immunologist
National Naval Medical Center
Bethesda, MD 20889

- **Provides Allergy/Immunology specialty care** to military beneficiaries as a staff physician
- **Supervises nurses/enlisted personnel in terms of skin testing and pulmonary function testing**

5. PROFESSIONAL EXPERIENCE

2006-2007 Medical Officer
Division of Scientific Investigations
Good Clinical Practice 2
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993
301-796-3402

Responsibilities

- Served as **Medical Officer (O-6 billet)** in the Division of Scientific Investigations
- Responsible for a full range of FDA compliance enforcement activities related to FDA regulations covering Bioresearch Monitoring (BIMO) Inspection Program.
- Evaluated and facilitated inspections related to New Drug Applications (NDAs), new Biologic license applications (BLAs), supplements and amendments.
- Reviewed Establishment Inspection Reports (EIRs), assesses evidence, determines nature of violations and initiates appropriate regulatory or legal actions for conformance with enforcement policy and regulatory objectives.

Accomplishments

- Supported the evaluation of 8 NDAs and 1 BLA by issuing assignments for clinical inspections and made critical recommendations on data integrity for marketing applications
- Worked up a complicated case for enforcement actions against a clinical investigator which resulted in a Warning Letter to the investigator for significant issues with compliance with regulations and Good Clinical Practice guidelines
- Evaluated several complaints regarding good clinical practices with respect to clinical investigations and has sent out 7 regulatory letters to the respective investigators
- Actively participated in 2 work groups related to the Division's internal review processes
- Initiated a training manual for new employees in DSI from paper to an electronic format using web-based design
- Provided training to DSI employees in the use of the Electronic Document Room in review of NDAs
- Presented to the Division of Pulmonary and Allergy Products and the Division of Non-Prescription Products on DSI's role in BIMO and in review of NDAs. Additionally, successfully completed the BIMO course in July 2007 and presented two lectures at this (Assignment Process & Sponsor Investigators).
- Presented to NIAID researchers on DSI's role in BIMO and investigator responsibilities. Presented at DSI's Case Presentation on Navigating the Electronic Document Room.
- Actively Participated in DSI's Strategic Initiatives Retreat & Subsequent Outcomes Meetings.

2002-2006

Medical Officer

Division of Pulmonary and Allergy Drug Products
HFD-45, Center for Drug Evaluation and Research, FDA
10903 New Hampshire Avenue
Silver Spring, MD 20993
(301)-796-1275

Responsibilities

- Served as **Medical Officer (O-6 billet)** in the Division of Pulmonary and Allergy Drug Products
- Responsible for the **medical evaluation and review of drugs** required by the **Food, Drug, and Cosmetic Act**, which **must precede the approval of a drug** for investigational use and commercial marketing.
- **Evaluated Clinical Trials of drugs for investigational use** (IND, Investigational New Drug) and for **commercial marketing** (NDA, New Drug Application) and provides **guidance to applicants** on the design of their development programs for these drugs.
- Reviewed and **determines whether protocols for proposed clinical trials in Investigational New Drug applications (IND)** are soundly conceived and supported by data to **justify tests on humans**
- **Evaluated data from human drug clinical trials** submitted in **New Drug Applications (NDA) for evidence of safety and effectiveness** in order to determine if the drug should be approved for general public use
- **Reviewed proposed labeling** and labeling changes to determine if claims are truthful and if it provides **appropriate directions** for use and **warnings against misuse**
- **Served as a consultant** to other medical specialists and scientists **within the FDA and other government agencies**

Accomplishments

- Completed ~17 pre-IND meeting, and 26 Investigational New Drug applications (IND)
- Reviewed 6 NDA/sNDAs
 - Reviewed an **NDA Supplement that resulted in maintenance of precautions in the label, thus preventing potential problems for a common antihistamine**
 - **Received the PHS Citation for the exemplary review of this application**
 - **Review of an NDA resulted in the approval of the first HFA non-albuterol bronchodilator for the treatment of symptoms of COPD**
- **Completed 9 consultations** to other Divisions within the Agency **drawing on her expertise in Allergy/Immunology and providing critical advice** on matters relating to marketing/advertisement, study design, and **maintenance of precautionary statements in existing labels to ensure the safety of drugs**
- Has participated in numerous teleconference with an individual investigator where several safety concerns were identified; **this led to the inactivation of this IND, preventing potential harm to subjects**
- Has participated in **teleconferences with several pharmaceutical companies, resulting in appropriate amendments** to the submitted protocols **to address the safety concerns identified**
- **Reviewed of over 450 sample prescriptions** as member of the **Prescriptions Studies Workgroup** to evaluate for **potential prescription errors, a great public health concern**
- **Completed 14 FDA offered classes in a short period of time demonstrating unwavering commitment to a career in the USPHS**

- **Resulted in better understanding of the review process and the ability to write thorough reviews and present data in a useful format**
- **Served as lead spokesperson for the Division providing sponsors with vital information at critical stages of drug development**
- **Reviewed over 500 submissions such as new protocols, annual reports, safety reports, and study reports**
- **Initiated and leading a monthly Immunology review group for colleagues in the Division to help prepare them for anticipated reviews of new immunologic mediators as potential drugs**
- **Division Coordinator to spearhead educational meetings with Division of Drug Marketing, Advertising, and Communications**
- **Organized 2 sessions and facilitated 1 session at the Office of New Drugs' Clinical Reviewer's Retreat**

1999-2002 **Service Chief, Allergy/Immunology**
National Naval Medical Center
8901 Wisconsin Ave, Bethesda, MD 20889

Responsibilities

- **Provided allergy, asthma and immunology outpatient and inpatient specialty care for adults and children of military beneficiaries and Congressmen**
- **Sole Navy Allergy/Immunology Consultant in the National Capital Area**
- **As Service Chief, co-responsible for all administrative aspects of the service with service manager**
- **Supervised clinic nurses, enlisted personnel, receptionists, and service manager in terms of both clinical and administrative functions**
- **Provided In-Service Training to personnel**
- **Responsible for Credentialing other Allergists/Immunologists at NNMC**
- **Service was responsible for Annual Flu Immunization to military dependents and retirees (1999,2000)**
- **Responsible for Immunizations for pediatrics, travel clinic, dependents and retirees (1999-2001)**
- **Provided Allergy/Immunology services at United States Naval Academy on Indoctrination Day (1999,2000,2001,2002)**
- **Allergy/Immunology consultant to the Office of the Attending Physician, U.S. Capitol, 2002-present**

Accomplishments

- **Successfully re-started a fully functioning Allergy/Immunology Service at National Naval Medical Center for both adult and pediatric patients, after an almost 2 year hiatus without a full time allergist**
- **Promoted customer service by providing for daily walk-in allergy shots**
- **Increased appointment compliance by 50% as a result of implementing a telephone call back system**
- **Substantially increased work efficiency by computerizing allergy extract new prescriptions and refills**
- **Provided Consultation to the U.S. Capitol, Office of the Attending Physician, for Allergy Immunotherapy Chart Review (2002)**
- **Successfully desensitized several individuals for drug allergy where other alternative was not possible**
- **Achieved 95% in patient satisfaction surveys initiated in 2002**
- **Successfully ensured organization of Annual Flu Vaccine Drive at NNMC, 1999,2000**
- **Worked with Facilities to design the new Allergy/Immunology Service spaces to provide for a fully functional clinic**
- **Served on the National Capital Consortium's Committee to screen nominees for the position of a new program director for the Walter Reed Army Medical Center Fellowship Program in Allergy/Immunology**
- **Successfully completed Navy's Management Development Course for Supervisors/Department Heads which resulted in direct implementation of leadership skills**
- **Was recognized as only one of two clinics in the whole hospital for excellence in record keeping and compliance on a mock JCAHO inspection resulting in approval to attend a National Allergy Professional Meeting**

6. APPOINTMENTS

2003-2004 **Allergy/Immunology Consultant to the U.S. Capitol,**
Office of the Attending Physician, U.S. Capitol
Washington, D.C.

- **Provide Allergy/Immunology specialty care to Members of Congress**
- **Review Allergy shot records for quality assurance purposes**

2000-2002 Assistant Professor of Medicine
Uniformed Services University of Health Sciences (USUHS)
F. Herbert School of Medicine
4301 Jones Bridge Road
Bethesda, MD 20814

- **Preceptor for 3rd year Internal Medicine Clerkship** medical students (2000,2002)
- **Preceptor for 2nd year medical students** taking physical diagnosis (2001)
- **Received the James J. Leonard Teaching Award (2002) for Excellence in Teaching Internal Medicine**
- **Provided several Allergy/Immunology Lectures to the Internal Medicine Interns and Residents**

7. PRIOR MILITARY SERVICE

United States Navy

- **Allergist-Immunologist, Medical Corps**
- Active Duty Time: June 1994-July 31, 2002, **Honorable** Discharge
- Highest rank held: **Lieutenant Commander, O-4 (permanent rank)**

8. MEDICAL LICENSES

- Virginia, active status

9. PROFESSIONAL SOCIETY MEMBERSHIPS

- American Academy of Allergy, Asthma and Immunology
Member, 2000-present
- American College of Allergy, Asthma and Immunology
Fellow, 2000-present
- American College of Physicians
Member, 1997-2004
- American Medical Association
Member, 1997-2004
- Greater Washington Allergy, Asthma and Immunology Society
Member, 2001-present

10. CERTIFICATIONS

Medical Specialty

- **American Board of Allergy and Immunology** 1999, scored in **95th percentile**; recertified in 2009
- **American Board of Internal Medicine**, 1997

Other Certifications

- **Basic Life Support**, 1994-present (expiration in 2012)
- **Advanced Cardiac Life Support**, 1994-present (expiration in 2012)
- **Advanced Trauma Life Support**, 1995
- Completion of **Combat Casualty Care Course** 1995

11. PHS SUPPORT AND OUTSIDE ACTIVITIES

- **PPAC Chair, 8/09 to present; Vice-Chair, PPAC: 2007-2009; Voting member, starting 6th year in 2010**
 - **Voting member of the PPAC**, second term starting January 2008
 - Chair of Career Development and Training Subcommittee: developed Welcome Packet and developed and maintained active mentoring list
 - **Voting member of the PPAC**, term starting in January 2005
 - Served on two **Subcommittees for Physician's Professional Advisory Committee (PPAC): Mentoring and Promotion Analysis**, 2004
- **Commissioned Corps Medical Category Appointment Board**, 2007-present
- Served on **Transformation Working Policy & Design Group** for the **Secretary's Transformation Plan**, 4/06-9/08 (received the Unit Commendation medal)
- Represented COA as Physician Volunteer for **NBC 4 Health and Fitness Expo**, 2007
- Active member of **Toastmaster's International**, completed **Certified Toastmaster Certificate** (Competent communicator), 2005
 - Sponsored a new club at White Oak Campus for FDA employees; served as President 2005-2006

- Served as Treasurer for Parklawn Toastmaster's Club
- Served as **one of two commissioned corps officers** measuring height, weight, and measurements to calculate BMI and Body Fat for interested officers as member of **COA**, 2004
- **Physician Volunteer** for **Montgomery County Asian American Health Fair**, 2004, 2005
- **Physician Volunteer** for **Asthma Fair** as member of American College of Allergy, Asthma, and Immunology, 2003, 2004, 2005
- Montgomery County **Science Fair Judge** representing **COA**, 2003, 2004, 2006, &2007
- **FDA representative** on the **Board of Directors**, Healthy Beginnings Child Development Center, 2003-present
- Volunteer for the **HHS and Arlington County Vaccination Site Test Exercise** (2003)
- Active member of the **Ceremonial Unit of the Surgeon General's Honor Corps**, 2002-present
- Participated as member of the **Associate Recruiter's Program** for the Commissioned Corps, 2002-2009; received **Recruitment Service Ribbon**, 2009
- **Staff Physician, Allergy/Immunology**, National Naval Medical Center, 2002-present
- **Volunteer for Everyone Wins**, Elementary School Reading **Mentoring Program** 2002-present
- **DPADP representative** for **Combined Federal Campaign** (CFC), 2002
- Member of **COA** 2002-
- Member of **AMSUS** 2002-
- Member of **ROA** 2002-
- **CFC (Combined Federal Campaign) keyworker** for Division of Pulmonary and Allergy Drug Products (Fall 2002)
- Member of **Drug Safety Prescription Studies Working Group** 2002-present
- Volunteer for **ODE II-III/Winterfest** (Winter 2002)
- Volunteer for **FDA sponsored Everyone Wins, elementary school mentoring program**
 - A **community –based** program where volunteers spend a lunch hour **reading to elementary school students** (2002-2005)

12. READINESS

- **Consistently meets OFRD basic readiness standards and completed all requirements for the previously defined intermediate and advanced readiness standards for CCRF/OFRD; completed the Medical Management of Chemical and Biologic Casualties Course**
- **Deployed for CCRF/OFRD for the World War II Veterans Memorial Dedication and Inauguration Day 2005; was slated to deploy for Katrina, but team was disbanded; volunteered for Inauguration Day 2009 participation, but not deployed**
- **Completed President's Challenge Active Lifestyle, Bronze, Silver, and Gold programs**
- **ACLS and BLS certified**
- **Armed Forces Combat Casualty Course, Fort Sam Houston, TX, 1995**

13. AWARDS AND HONORS

Uniformed Services Awards

- **PHS Special Assignment Award (2010)**
- **PHS Recruitment Service Award (2009)**
- **PHS Commendation Medal (2008)**
- **PHS Unit Commendation Medal (12/2008)**
- **PHS Unit Commendation Medal (10/2008)**
- **PHS Regular Corp Ribbon (2007)**
- **PHS Commendation Medal (2005)**
- **PHS Unit Commendation Medal (2005)**
- **PHS Surgeon General's Exemplary Service Medal (2004)**
- **PHS Citation (2003)**
- **PHS Surgeon General's Certificate of Appreciation (2003)**
- **Navy and Marine Corp Meritorious Unit Commendation Medal (2003)**
- **Commissioned Corps Training Ribbon (2002)**
- **Navy and Marine Corps Commendation Medal (2002)**
- **Navy and Marine Corp Meritorious Unit Commendation Medal (2002)**
- **National Defense Ribbon (2002)**
- **Navy and Marine Corp Meritorious Unit Commendation Medal (1995)**
- **National Defense Ribbon (1995)**

Other Awards and Honors

- **Letter of Appreciation, FDA Center Director, Center for Drug Evaluation and Research (2009)**
- **Presidential Champion Award Gold Award**
- **FDA Commissioner's Special Citation (2008)**
- **Physicians PAC Certificate of Appreciation (2008)**
- **White Oak Commissioned Corps Advisory Group Certificate of Appreciation (2008)**
- **Letter of Appreciation, FDA's Office of Regulatory Affairs (2008)**
- **Acting SG's notice of Recognition of Service as member of Working Policy and Design Group (2007)**
- **Flag Letter of Appreciation, HRSA, RADM Kerry Nessler (2007)**
- **Memorandum of Appreciation, Medical Category Appointment Board Secretary (2007)**
- **Certification of Appreciation from COA for service as Science Fair Judge (2007)**
- **Certification of Appreciation from COA for service as volunteer at NBC 4 Health and Fitness Expo (2007)**
- **Flag Letter of Appreciation from Director, OCCFM, RADM Canton (2006)**
- **Certification of Appreciation from COA for service as Science Fair Judge (2006)**
- **Letter of Appreciation from Director, Grants Program, Office of Orphan Products Development, FDA (2006)**
- **Certification of Appreciation from COA for service as Science Fair Judge (2005)**
- **Flag Letter of Appreciation from Surgeon General, VADM Carmona for Inauguration Response (2005)**
- **Thank You Letter from FDA Incentive Awards Program Coordinator (2005)**
- **Letter of Appreciation from Dr. Martin Luther King Jr. Commemorative Committee (2005)**
- **Flag Letter of Commendation, Navy (2004)**
- **Flag Letter of Appreciation from FDA Representative to the SG's Policy Advisory Council (2004)**
- **Letter of Appreciation, NNMC/Allergy Department Head (2004)**
- **Letter of Thanks from Division Director, Division of Pulmonary and Allergy Products (2004)**
- **Certificate of Appreciation from Everybody Wins DC Children's Literacy and Mentoring Program (2004)**
- **Certification of Appreciation from COA for service as Science Fair Judge (2004)**
- **Presidential Champion Award Bronze Award (2004)**
- **Presidential Champion Award Silver Award (2004)**
- **Letter of Recognition from Greater Washington Asthma, Allergy, & Immunology Society (2003)**
- **Certificate of Appreciation from Everybody Wins DC Children's Literacy and Mentoring Program (2003)**
- **Letter of Appreciation from Dr. Martin Luther King Jr. Commemorative Committee (2003)**
- **Certification of Appreciation from COA for service as Science Fair Judge (2003)**
- **Letter of Appreciation, National Capital Consortium, USUHS (2002)**
- **Letter of Appreciation, Naval Medical Clinic, Annapolis, MD (2002)**

- **USUHS James J. Leonard Award for Excellence in Teaching** Internal Medicine (2002)
- **Letter of Appreciation**, Naval Medical Clinic, Annapolis, MD (2000)
- **Department of Army, Certification of Appreciation** for National Capital Area Asthma and Allergy Fair (1998)
- Graduated **Cum Laude** from University of Maryland (1989)
- Awarded Title of **Dean's Scholar** (1989)
- **Dean's List all semesters** at University of Maryland
- **Certificate of Scholarship** awarded at **Annual Honors Convocation (1989)**
- Honor Societies
 - **Alpha Lambda Delta-Freshman Honor Society**
 - **Phi-Sigma-Biological Honor Society**
 - **Golden Key National Honor Society**
 - **Alpha Epsilon Delta-Premedical Honor Society**
 - **Phi Kappa Phi Honor Society**

13. LECTURES/PRESENTATIONS

Presentations as PHS Officer

- 2010: provided presentations to **19 FDA** internal and external customers
- Regulatory Affairs Professional Conference to include an Advisory Committee meeting 2010
- Annual Human Research Protection Program (sponsored by PRIM&R) 2008, 2009, 2010
- Investigational New Drug Regulations
 - Everything You Always Wanted to Know about What FDA Expects and Requires of Clinical Investigators
- CDER New Reviewer's Workshop 2010; 11/2009
- DSI and Bioresearch Monitoring 04/2008 and 11/2008
- American Academy of Allergy, Asthma and Immunology Annual Meeting 2/2010; 3/2009
- Good Clinical Workshop
- Society of Clinical Research Associates (SoCRA) 2010; 2009; 2009; 2008
- FDA Expectations of Clinical Investigators
- ORA Basic BIMO Course 2008, 2009, 2010
- DSI Assignment Process
 - Special Issues with Sponsor/Investigators)
- NIH NIAID 7/2007
- DSI's Role in BIMO/ FDA Expectations of Clinical Investigators

14. RESEARCH

Fellowship

- 1997 Assisted with *Purified Protein Derivative Delayed Type Hypersensitivity Skin Testing Compared to an In-Vitro Gamma Interferon Release Assay.*

15. PUBLICATIONS

Oral Allergy Syndrome. Allergy and Asthma Proceedings, **May-June 2005**; Vol. 26, No. 3

. *Cell Mediated Immune Response to Tuberculosis Antigens: Comparison of Skin Testing and Measurement of in vitro Gamma Interferon Production in Whole-Blood Culture.* Clin Diag Lab Immunol. 2001 Mar; 8(2): 339-45

16. PUBLICATIONS AS ABSTRACTS

. *Successful Graded Administration of Radiocontrast Media (RCM) in a Patient with an Anaphylactoid Reaction to Hypo-Osmolar RCM Despite Premedication.* Ann of Allergy Asthma and Immunol 1999; 82: 93

. *Stiff-Man Syndrome: Symptomatic Improvement with Intravenous Immunoglobulin (IVIG).* J All Clin Immunol 1999; 103, No.1, Pt. 2: S20

17. SCIENTIFIC PRESENTATIONS

. **Stiff-Man Syndrome: Symptomatic Improvement with Intravenous Immunoglobulin (IVIG).** Oral Presentation at 11th Annual Harold S. Nelson Allergy-Immunology Symposium and the 26th Association of Military Allergy Meeting. Orlando, FL. February 1999.

Stiff-Man Syndrome: Symptomatic Improvement with Intravenous Immunoglobulin (IVIG). Poster Presentation at American Academy of Allergy, Asthma, and Immunology National Meeting. Orlando, FL. February 1999.

. **Successful Graded Administration of Radiocontrast Media (RCM) in a Patient with an Anaphylactoid Reaction to Hypo-Osmolar RCM Despite Premedication.** Poster Presentation at American College of Allergy, Asthma, and Immunology Philadelphia, PA. November 1998.

. **Successful Graded Administration of Radiocontrast Media (RCM) in a Patient with an Anaphylactoid Reaction to Hypo-Osmolar RCM Despite Premedication.** Oral Presentation to Washington Area Allergy and Immunology Conference. NIH, Bethesda, MD. November 1998.

. **Stiff-Man Syndrome: Symptomatic Improvement with Intravenous Immunoglobulin (IVIG).** Oral Presentation at Army National American College of Physicians Meeting. Reston, VA. November 1998.

. **Successful Graded Administration of Radiocontrast Media (RCM) in a Patient with an Anaphylactoid Reaction to Hypo-Osmolar RCM Despite Premedication.** Oral Presentation at 10th Annual Harold S. Nelson-Allergy-Immunology Symposium and the 25th Association of Military Allergy Meeting. Washington, D.C. November 1997.

. **Chylothorax Presenting as Neck Mass.** Navy National American College of Physicians Meeting. San Diego, CA. November 1996

18. TRAINING/WORKSHOPS

Title	Sponsor	Dates
Leadership Development	FDA	12/10-present for 12 mos
Fraud in Clinical Trials	Barnett Educational Ser.	12/8-12/9/09
Reduce Stress Through Time Management	Dale Carnegie	9/15/09
Communication Seminar	Skill Path Seminar	8/31/09
Strategic Management of Regulatory and Enforcement Agencies	Harvard University	10/05-10/10/08
New Manager's Series	CDER/FDA	4/29-4/30/08
Basic Clinical Bioresearch Monitoring	FDA/ORA	7/24-8/1/07
Completed Competent Communicator Program	Toastmasters Int'l	2005
<u>FDA CDER Classes</u>		
Toxicology for Non-Toxicologists	CDER/FDA	10/2004
Introduction to Generic Drug Review and Regulations	CDER/FDA	10/2004
IND Regulations	CDER/FDA	2/2004
Successful Negotiations	CDER/FDA	11/20/03-11/21/03
Basic Topics in Statistics/ANOVA/Regression	CDER/FDA	10/7/03-11/18/03
NDA Regulations	CDER/FDA	6/23/03-6/25/03; 7/1/03
Clear Writing through Critical Thinking	PSC	4/29/03-5/1/03
Grammar Refresher	CDER/FDA	4/14/03
Technical Writing for Reviewers	CDER/FDA	3/4/03-3/6/03
Topics in Clinical Trials	CDER/FDA	2/28-5/23/2003
Basic Statistics	CDER/FDA	1/29-3/12/2003
Basic Drug Law	CDER/FDA	11/21-11/22/2002
Presenting Data	CDER/FDA	10/28/2002
New Reviewers' Workshop	CDER/FDA	10/2/2002-10/4/2002
New Employee Orientation	CDER/FDA	9/24/2002-9/30/2002
PK/PD Tutorial	CDER/FDA	9/23/2002

Intro to Clinical Trials/Design CDER/FDA 9/20/2002-12/13/2002

OIT Classes

Power Point Charts	OIT/FDA	9/12/2002
Microsoft Power Point	OIT/FDA	9/12/002
JMP II	OIT/FDA	9/11/2002
DFS	OIT/FDA	9/5/2002
JMP I	OIT/FDA	9/4/2002
NEST	OIT/FDA	8/29/2002
Microsoft Excel	OIT/FDA	8/28/2002
Outlook Calendar	OIT/FDA	8/21/2002
E-DOC Query/Retrieval	OIT/FDA	8/15/2002
Information System Security Training	CDER/FDA	8/12/2002
WORD Tables	OIT/FDA	8/8/2002
WORD Formatting	OIT/FDA	8/7/2002
Microsoft WORD	OIT/FDA	8/7/2002

USPHS

Medical Management of Chemical and Biologic Casualties	CCRF/US Army	9/12-9/17/2004
CCRF Core and Physician Modules	CCRF	2004
Independent Officers Training Course	COTA	10/10/-10/11/2002
Basic Officers Training Course	COTA	9/16-9/20/2002

19. CME

AAAAI Annual Meeting	AAAAI	2010	28.5	CME
ABAI Examination	ABAI	2009	25	CME
AAAAI & ACAAI Board Review Course	AAAAI/ACAAI	2009	29.5	CME
ABMS Patient Safety Improvement Program (Online)	ABIM	2009	20	CME
Pennsylvania Allergy & Asthma Association (PAAA) Annual	PAAA	2009	13.25	CME
Am Academy of Allergy, Asthma and Immunology (AAAAI)	AAAAI	2009	32	CME
Pennsylvania Allergy & Asthma Association (PAAA) Annual	PAAA	2008	13.25	CME
Frontiers in Asthma and Allergy	Johns Hopkins	2008	14.5	CME
American College of Allergy, Asthma, and Immunology	Philadelphia	2006	35.5	CME
Frontiers in Asthma/Allergy	Johns Hopkins	2006	14.5	CME
Frontiers in Asthma/Allergy	Johns Hopkins	2005	15.5	CME
COA Public Health Conference	PHS	2005	6.25	CME
CDER Seminars	CDER/FDA	2004	7	CME
Toxicology for Non-Toxicologists	CDER/FDA	2004	18	CME
Medical Management of Chemical and Biologic Casualties	US Army	2004	46.75	CME
CCRF Core and Physician Modules	CCRF	2004	43	CME
ANOVA and Regression	CDER/FDA	2003	12	CME
National Conference on Asthma 2003	NAEPP	2003	17	CME
Symposium on Pharmaceutical Aerosols	CDER/FDA	2003	12	CME
Topics in Clinical Trials	CDER/FDA	2003	18	CME
Basic Statistical Methods	CDER/FDA	2003	17	CME