

CURRICULUM VITAE SUMMARY

Name, MD, CDR, USPHS
Medical Category PHS#
Date

PERFORMANCE

- Medical Team Leader responsible for managing the activities of a team of 3 Medical Officers who evaluate the safety and efficacy of drugs for investigational use (IND) and for commercial marketing (NDA), O-6 billet
- Team of Medical Officers completed 1 NDA review, 24 IND reviews, 44 End-of-Phase 2, Pre-NDA, and Pre-IND submissions, and 5 consultations in the last year
- Personally completed 24 NDA and NDA supplement reviews, 28 IND reviews, 86 End-of-Phase 2, Pre-NDA, and Pre-IND submissions, and 55 consultations while serving at FDA, 1999-present
- Recent Honor and Unit Awards
 - USPHS Outstanding Service Medal, 2006
 - USPHS Commendation Medal: 2004, 2005, 2007
 - USPHS Achievement Medal: 2002
 - Navy and Marine Corps Achievement Medal: 2002
 - USPHS Outstanding Unit Citation, 2006
 - USPHS Unit Commendation: 2003, 2004, 2005
 - Navy and Marine Corps Meritorious Unit Commendation: 2003, 2004

EDUCATION, TRAINING, AND PROFESSIONAL DEVELOPMENT

Education

- Allergy Fellowship, Wilford Hall USAF Medical Center, TX, July 1989–June 1991
- Flight Surgeon, USAF School of Aerospace Medicine, Brooks AFB, TX, March 1990–April 1990
- Residency and Internship in Pediatrics, University of Maryland Hospital, Baltimore, MD, July 1980–June 1983
- M.D., University of Maryland School of Medicine, Baltimore, MD, August 1976–May 1980
- B.S., Microbiology, University of Maryland, College Park, August 1972–May 1976

Medical Licensure

- State

Certification

- American Board of Allergy & Immunology [year redacted], Recertified [year redacted]
- American Board of Pediatrics [year redacted], time unlimited

CAREER PROGRESSION AND POTENTIAL

- Medical Team Leader, FDA: Center for Drug Evaluation and Research, Division of [name redacted] Drug Products, Silver Spring, MD, 2006-present
- Medical Officer, FDA: Center for Drug Evaluation and Research, Division of Pulmonary and Allergy Drug Products, Rockville and Silver Spring, MD, 1999-2006
- Allergist-Immunologist, Private Practice: Georgetown, DE, 1995-1999
- Pediatrician, Allergist-Immunologist, A. I. duPont Institute: Georgetown, DE, 1994-1997
- Staff Physician, Allergy & Immunology, USAF: Travis AFB, CA, 1991-1994
- Pediatrician and Chief, Newborn Nursery, USAF: K. I. Sawyer AFB, MI, 1987-1989
- Pediatrician, Private Practice: Salisbury, MD, 1987
- Pediatrician, USPHS National Health Service Corps: DE and PA, 1983-1986

PROFESSIONAL CONTRIBUTIONS TO THE PHS COMMISSIONED CORPS (OFFICERSHIP)

- PHS Ensemble, 2002-present
- Staff Physician, National Naval Medical Center, Bethesda, MD, 2001-present
- Peer reviewer for the journal Military Medicine, 2002-present
- Member COA, AMSUS, ROA, 2001-present

READINESS

- OFRD readiness status basic, assigned to Tier 1 Asset, Emergency Management Group Alpha
- Field Medical Readiness Badge, 2007
- Deployed to Baton Rouge, LA in August 2005 in support of Hurricane Katrina relief efforts. One of the 37 PHS officers deployed with CAPT Charles McGarvey in the initial PHS response to Hurricane Katrina.
- Completed all required and optional OFRD training modules, four FEMA Emergency Management Institute courses, Medical Effects of Ionizing Radiation Course, and Homeland Security Medical Executive Course

CURRICULUM VITAE

Name:
Birth Place:
Rank: Rank, USPHS
PHS Number:

PRECEPT 1: PERFORMANCE

CURRENT POSITION

Medical Team Leader
Division of Pulmonary and Allergy Products
Center for Drug Evaluation and Research, FDA
Address
November 2006-present

- Serves as **Medical Team Leader** (O-6 billet) in the Division of [name redacted] Products (redacted), Center for Drug Evaluation and Research (CDER)
- **Principal advisor** to Division Director and other center managers on issues on pulmonary and allergy products
- Responsible for planning, coordinating, and evaluating medical programs and activities of a **team of three medical officers** within DPAP
- Advises, counsels and instructs team members on significant concepts of medical science, procedures, guidelines, and policies
- Medical team is responsible for:
 - **Evaluation of the safety and efficacy** of drugs for investigational use (IND) and for commercial marketing (NDA) that are to be used by millions of Americans, including antihistamines such as Allegra and Claritin, allergy nasal inhalers, and asthma inhaler medications
 - Providing **guidance to industry** on the design of their development programs for these drugs
 - Reviewing proposed labeling and labeling changes to **determine if claims are truthful** and if they provide appropriate directions for use and warnings against misuse
 - Serving as a consultant to other medical specialists and scientists within the FDA and other government agencies

Accomplishments in the last year:

- Promoted to **Medical Team Leader** position
- **Managed and provided leadership**, scientific guidance, and secondary review for team of 3 Medical Officers
 - Team accomplishments in the last year:
 - Completed 1 NDA review leading to an “Approvable” action for an antitussive drug. Review **identified** increased systemic exposure to the antitussive when it was administered with food; a **potential safety problem**. Increase in systemic exposure precluded approval of the application.
 - Provided **critical guidance** to sponsors on trial design and drug development in 44 Pre-IND, End-of-Phase 2, Pre-NDA, and advice meetings

- Completed 24 IND reviews, insuring studies met their objectives and safety of subjects was maintained
- Reviewed 4 Special Protocol Assessments (SPA), assessing whether the protocols were adequate to meet regulatory and scientific requirements. SPAs are considered to be binding on the review division.
- Completed 5 consultations, providing analysis and recommendations for other Center for Drug Evaluation and Research (CDER) Divisions
- Personal accomplishments in the last year:
 - Completed review and **clinical lead** for 1 NDA, leading to "**Approval**" action for a new allergy drug and 1 NDA labeling supplement adding a boxed warning and **important safety information** to the label of the drug (name redacted)
 - Provided **critical guidance** to sponsors on trial design and drug development in 5 Pre-IND and advice meetings
 - Completed 4 IND reviews, insuring studies met their objectives and safety of subjects was maintained
 - Completed 1 SPA review, assessing whether the protocol was adequate to meet the regulatory and scientific requirements identified by the sponsor
 - Composed 1 Written Request for pediatric studies, requesting the sponsor to conduct clinical studies to provide **needed information** on the use of an intranasal allergy drug **in children**
 - Completed 3 consultations, providing analysis and recommendations for other Center for Drug Evaluation and Research (CDER) Divisions
 - **Clinical lead** for Regulatory Briefing on anaphylaxis adverse events for CDER Senior Management Staff
 - **Co-authored** scientific publication on anaphylaxis associated with the drug (name redacted)
 - DPAP **co-representative** for Combined Nonprescription Drug Advisory Committee and Pediatric Advisory Committee Meeting on the safety of cough and cold medications in children
 - Awarded PHS Commendation Medal for analysis of anaphylaxis reports and development of labeling to **ensure the safe use** of the drug (name redacted)
 - Awarded Outstanding Unit Citation for participation in medical response to Hurricane Katrina while deployed to Baton Rouge, LA
 - Awarded Special Assignment Award for support activity as member of PHS Music Ensemble
 - Awarded the Crisis Response Service Award for medical response to the Gulf Coast Hurricanes, 2005
- Selected as 2007-2008 **Council for Excellence in Government Fellow**, a program to develop talented leaders and to improve the performance of government and government's place in the lives and esteem of American citizens
- Selected for and completed FDA Formula for Achieving **Managerial Excellence Leadership Skills** Training
- **Exceptional COER** while serving at the O-5 grade in an **O-6 billet**

Accomplishments since coming to the FDA:

- Completed reviews and clinical lead for 24 NDA and NDA supplements, assisting the Division in approval, approvable, and not approvable actions, including approvals of (drug name redacted) for over-the-counter (OTC) marketing, **boxed warning** and

- important safety information** on the use of the drug (drug name redacted), and pediatric-friendly formulations of the antihistamine (drug name redacted), among others
- Completed reviews and **clinical lead** for 28 IND applications allowing investigational studies to proceed or resulting in clinical holds or withdrawal of applications that included studies that were not safe to proceed
 - Completed reviews and **clinical lead** for 86 End-of-Phase 2, Pre-NDA, Pre-IND, and other submissions and participated in the subsequent meetings providing scientific guidance for the sponsors
 - Completed 55 consultations and **Division lead** providing assistance to other CDER Divisions, Office of Compliance, CDER Executive Operations Staff, and CDRH
 - Drafted 4 Written Requests for Pediatric Studies for the drugs (drug name redacted) (2 Written Requests), (drug name redacted) Nasal Spray, and a currently unapproved antihistamine nasal spray, requesting the sponsors to perform studies to provide **needed information** on use of these drugs in the **pediatric population**
 - Completed 3 SPAs for allergy and asthma drugs, assessing whether the protocol was adequate to meet the regulatory and scientific requirements identified by the sponsor
 - Provided **testimony at deposition and trial** as expert witness for FDA in case against Pharmakon, Inc., a manufacturer of unapproved and **illegal drug products**. The testimony was instrumental in U.S. District Court Judge Richard A. Lazzara's order for a permanent injunction against the company, which shut down operations at the firm and resulted in the **destruction of 160,000 lbs. of illegal drug products**.
 - Prepared and presented a briefing for the **Pediatric Implementation Team** regarding an applicant's decision to decline to a Written Request for Pediatric studies for an antihistamine used for the treatment of allergic rhinitis and pediatric studies for an inhaled corticosteroid for treatment of asthma
 - Prepared a review and delivered a presentation for the **Pulmonary/Allergy Drugs Advisory Committee**, January 2002, regarding an indication for the inhaled drug **Flovent** for the treatment of chronic obstructive pulmonary disease
 - Prepared the background summary on the **OTC indication for** (drug name redacted) for the **Nonprescription Drugs and Pulmonary/Allergy Drugs Advisory Committee** and participated in the Advisory Committee meeting, April 2002
 - Selected for and completed FDA Formula for Achieving Managerial Excellence **Supervisory Potential** Workshop

Additional FDA Activities

- Division of [redacted] Drug Products Pediatric Exclusivity Working Group, 1999-present
- **Lead** for CDER Guidance for Allergic Rhinitis Drug Development Programs, 2004-present
- CDER Prescription Studies Working Group Member, 2000-present
— Completed 549 interpretations of drug proprietary names
- CDER Pediatric Committee, Division of Pulmonary and Allergy Drug Products **co-representative**, 1999-2004
- CDER OTC Antihistamine Switch Review Team, 2000
- CDER Sedating Prescription Drugs Working Group Member, 2002-2003
- Division of Pulmonary and Allergy Drug Products Epidemiology **Coordinator**, 1999-2005

PHS PROMOTION

- Commander, temporary, 2004
- Lieutenant Commander, temporary, 2001

- Lieutenant Commander, permanent, 2001

AWARDS AND HONORS

Uniformed Services Awards, in order of precedence

- USPHS Outstanding Service Medal
 - Critical expert scientific and regulatory input in the trial of U.S. v Pharmakon Laboratories, Inc., 2006
- USAF Meritorious Service Medal
 - Performance of outstanding service as Staff Allergist/Immunologist, Allergy and Immunology Clinic, David Grant USAF Medical Center, Travis AFB, CA, 1994
- USPHS Commendation Medal
 - Analysis of anaphylaxis reaction reports and development of labeling to ensure safe use of the drug Xolair, 2007
- USPHS Commendation Medal
 - Continuous outstanding scientific and regulatory contributions to the U.S. Food and Drug Administration in the completion of medical officer consultations, 2005
- USPHS Commendation Medal
 - Exceptional and sustained scientific contributions to the U.S. Food and Drug Administration in the performance of scientific consultations in the field of Allergy and Immunology, 2004
- USAF Commendation Medal
 - Meritorious service as Pediatrician, K. I. Sawyer AFB, MI, 1989
- USPHS Achievement Medal
 - Superior performance and achievement in duties at the Allergy and Immunology Clinic, National Naval Medical Center, Bethesda, MD, 2002
- Navy and Marine Corps Achievement Medal
 - Professional achievement, performance, and leadership as Staff Physician in the Allergy and Immunology Clinic, National Naval Medical Center, Bethesda, MD, 2002
- USPHS Outstanding Unit Citation
 - Protecting the public health of the citizens of Louisiana, Texas, Florida, and Mississippi after Hurricanes Katrina, Rita, and Wilma, 2007
- Air Force Outstanding Unit Award
 - David Grant USAF Medical Center, Travis AFB, CA, 1994
- USPHS Unit Commendation
 - Dedication and diligence to promote the Commissioned Corps through the real and imaginative expressions of music, 2005
- USPHS Unit Commendation
 - Contributing to the creation of a risk management program to assure the safe use of Plenaxis, 2004
- USPHS Unit Commendation
 - Exceptional communication and coordination of the review and approval of NDA supplements for the OTC switch of Claritin brand (loratadine) drug products, 2003
- Navy and Marine Corps Meritorious Unit Commendation: 2004
 - Service in support of Operations ENDURING FREEDOM and IRAQI FREEDOM over the period of 15 December 2002 to 15 September 2003, 5/2004
- Navy and Marine Corps Meritorious Unit Commendation: 2003

- For provision of uninterrupted medical care and services by the National Naval Medical Center staff while supporting the Office of the Attending Physician to Congress in response to anthrax attacks
- USPHS Special Assignment Award: 2007
 - Completion of 30 non-consecutive days of administrative, performance/rehearsal, and/or support activity with the PHS Ensemble
- USPHS Crisis Response Service Award: 2006
 - Response to Gulf Coast Hurricanes (Katrina, Rita, Wilma) in Mississippi, Louisiana, Texas, and Florida
- National Defense Service Medal, USAF: 1991
 - Service during Persian Gulf War I
- USPHS Regular Corps Ribbon: 2006
- Commissioned Corps Training Ribbon: 2002
- Air Force Training Ribbon, USAF: 1987
- Field Medical Readiness Badge: 2007
 - Demonstration through training, physical fitness, and other requirements necessary to be an effective responder
- Air Force Flight Surgeon, USAF: 1989
 - Honor graduate (First in Class)

Other Awards and Honors

- AMA Physician's Recognition Award for Continuing Medical Education, 2007
- Letter of Thanks from RADM Wyatt, NIH representative to the Office of the Surgeon General, for participation in NIH Commissioned Corps Officer Promotion Ceremony, July 2007
- Letter of Thanks from RADM Williams, Chief of Staff Office of the Surgeon General, for participation in Commissioned Corps Wind Ensemble at Memorial Service for RADM Knouss, July 2007
- Surgeon General's Certificate of Appreciation from RADM Moritsugu for outstanding service and musical contributions to the Office of Surgeon General while serving in the USPHS Commissioned Corps Music Ensemble, December 2006
- Letter of Appreciation from Surgeon General, VADM Richard Carmona, for support at the Inauguration of President George W. Bush, January 2005
- Letter of Thanks from CAPT Murphy, Chief Commissioned Corps Operations Staff, for participation in Commissioned Corps Wind Ensemble at HRSA Commissioned Corps Promotion Ceremony, August 2004
- Letter of Appreciation from RADM Haffner, FDA Representative to Surgeon General's Policy Advisory Council, for participation in Commissioned Corps Wind Ensemble at Promotion Ceremony of RADM Steven Galson, March 2004

Other Awards and Honors, continued

- Letter of Appreciation from CAPT Hamilton Brown, Executive Director, Anchor and Caduceus Society, for participation with the Commissioned Corps Ensemble at the annual meeting and luncheon, January 2004
- AMA Physician's Recognition Award for Continuing Medical Education, 2002
- Letter of Appreciation from RADM Haffner, FDA Representative to Surgeon General's Policy Advisory Council for participation in Commissioned Corps Wind Ensemble at FDA Commissioned Corps Promotion Ceremony, July 2002

- CDER Team Excellence Award as a member of a working group that reviewed the safety databases for three prescription antihistamines proposed for a possible switch to over-the-counter marketing status, May 2002
- CDER Center Director's Special Citation for reviewing and interpreting drug proprietary names in its effort to reduce medication errors, November 2001
- FDA On-the-Spot Award for review of a prostate cancer drug associated with anaphylaxis, May 2001
- One of four of Delaware's Top Allergists, *Delaware Today Magazine*, 1998
- Second place award for abstract by a Fellow in Training, Southwest Allergy Forum, San Antonio, TX, April 1991
- Alpha Omega Alpha, 1979
- Phi Beta Kappa, 1976
- Phi Kappa Phi, 1975
- Sigma Alpha Omicron, Microbiology Honor Society, 1975

PRECEPT 2: EDUCATION, TRAINING, AND PROFESSIONAL DEVELOPMENT

EDUCATION

University of Maryland School of Medicine
Baltimore, MD
MD, 1980

University of Maryland
College Park, MD
BS, Microbiology, 1976

TRAINING

Allergy-Immunology Service
Wilford Hall USAF Medical Center
Lackland AFB, TX
Fellow, July 1989-June 1991

USAF School of Aerospace Medicine
Brooks AFB, TX
Aerospace Medicine Primary Course (Flight Surgeon)
Honor Graduate (First in class)
April 1989

TRAINING, continued

University of Maryland Hospital
Baltimore, MD
Resident, Pediatrics
July 1981-June 1983

University of Maryland Hospital
Baltimore, MD
Intern, Pediatrics
July 1980-June 1981

MEDICAL LICENSES

State, active status
State, inactive status
State, inactive status

PROFESSIONAL SOCIETY MEMBERSHIPS

American Academy of Allergy and Immunology, Fellow, 2006-present, Member, 1989-2006
American College of Allergy and Immunology, Fellow, 1992-present
American Academy of Pediatrics, Fellow, 1986-present
American Academy of Pediatrics Section on Allergy and Immunology, Member, 1992-present
Commissioned Officers Association of the U.S. Public Health Service, Member, 2001-present
Association of Military Surgeons of the U.S., Member, 2001-Present
Reserve Officers Association, Member, 2001-Present

CERTIFICATIONS

Medical Specialty

Board-certified in Allergy and Immunology and Pediatrics

- American Board of Allergy and Immunology 1991, Recertified 2001
- American Board of Pediatrics, 1985

Other Current Certifications

Basic Life Support, 2007

Previous Certifications

Pediatric Advanced Life Support, 1997
Advanced Cardiac Life Support, 1993
Advanced Trauma Life Support, 1988
Combat Care Casualty Course (C4), 1988

INSERVICE TRAINING AND WORKSHOPS

Title	Sponsor	Dates
Fellow, Council for Excellence in Government	CEG	10/2007 to present
FAME Leadership Skills I	FDA	9/17/07 to 9/21/07
Homeland Security Medical Executive Course	DMRTI, USF	6/12/06 to 6/16/06
AAAAI Annual Meeting, 2006	AAAAI	3/3/06 to 3/8/06
2006 Military Allergy Program	AAAAI	3/2/06
Supervisory Potential Leadership Course	FDA	3/14/05 to 3/18/05
Frontiers in Asthma and Allergy	Johns Hopkins	6/10/05 to 6/11/05
Medical Effects of Ionizing Radiation	AFFRI	8/3/0 to 8/6/04
Drug Law	FDLI	12/18/03 to 12/19/03
Clinical Reviewers Workshop	CDER/FDA	11/17/03
Continuous Marketing Applications Training	CDER/FDA	10/17/03
National Conference on Asthma 2003	NHLBI	6/19/03 to 6/21/03
Tools for Pre-Approval Drug Safety Workshop	CDER/FDA	4/29/03 to 5/27/03

Title	Sponsor	Dates
The Label and Beyond--Risk Communication	CDER/FDA	6/13/02
Economic Assessment in Controlled Clinical Trials	CDER/FDA	5/8/02
Frontiers in Asthma and Allergy	Johns Hopkins	4/26/02 to 4/28/02
Best Pharmaceuticals for Children Act	CDER/FDA	4/15/02
Diagnostic Clinical Trials	CDER/FDA	3/26/02 to 5/14/02
Topics in Clinical Trials	CDER/FDA	3/22/02 to 5/15/02
European Drug Regulatory System	CDER/FDA	3/13/02
Bioterrorism	CDER/FDA	2/22/02
Human Pregnancy Outcome Data	CDER/FDA	11/14/01
Clinical Reviewer Retreat/Workshop	CDER/FDA	10/30/01 to 10/31/01
Introduction to IMS Health	IMS	10/15/01
QT Prolongation Workshop	CDER/FDA	5/15/01 to 6/5/01
Review for the ABAI Recertification Exam	ACAAI	4/27/01 to 4/29/01
Clinical Pharmacology During Pregnancy	CDER/FDA	12/4/00 to 12/5/00
Introduction to Drug Law and Regulation	PERI	11/13/00 to 11/14/00
Regulatory Science	CDER/FDA	10/12/00 to 11/2/00
Design and Conduct of Clinical Trials	CDER/FDA	9/29/00 to 12/8/00
Health Related Quality of Life Measures	CDER/FDA	9/28/00
Frontiers in Asthma and Allergy	Johns Hopkins	3/31/00 to 4/2/00
New Reviewer's Workshop	CDER/FDA	2/16/00 to 2/24/00
Technical Writing for Reviewers	CDER/FDA	2/8/00 to 2/10/00
Basic Statistical Methods	CDER/FDA	9/22/99 to 11/8/99

PRECEPT 3: CAREER PROGRESSION AND POTENTIAL

PREVIOUS PROFESSIONAL EXPERIENCE

Medical Officer, USPHS Commissioned Corps
Division of [name redacted] Products
Center for Drug Evaluation and Research, FDA
Address
October 2005-November 2006

Address

July 2001-September 2005

- Served as Medical Officer (O-6 billet) in the Division of [name redacted] Drug Products, Center for Drug Evaluation and Research (CDER)
- Responsible for **evaluation of the safety and efficacy of drugs** for investigational use (IND) and for commercial marketing (NDA) that are to be used by millions of Americans, including antihistamines such as Allegra and Claritin, allergy nasal inhalers, and asthma inhaler medications
- Provided **guidance to applicants** on the design of their development programs for these drugs
- **Reviewed proposed labeling** and labeling changes to determine if claims are truthful and if they provide 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

Medical Officer, civilian appointment
Division of [name redacted] Drug Products
HFD-[redacted], Center for Drug Evaluation and Research, FDA
Address

June 1999-July 2001

- Responsibilities and accomplishments as noted above in "PREVIOUS PROFESSIONAL EXPERIENCE"

Allergist-Immunologist
Sussex Allergy, Asthma, & Immunology
Address

August 1995-May 1999

- Provided allergy and immunology **specialty care** for adults and children
- **Supervised and trained** office nurses, receptionists, and office manager
- Performed accounting and bookkeeping
- Established the **only board-certified allergy practice** in Sussex County, Delaware
- Chosen as **one of four of Delaware's Top Allergists** by peers for *Delaware Today* magazine, October 1998
- **President** of the Asthma & Allergy Society of Delaware, 1998

PREVIOUS PROFESSIONAL EXPERIENCE, continued

Pediatrician

A. I. duPont Institute Children's Clinics
15 Georgetown Plaza Shopping Center
Georgetown, DE 19947

August 1994–May 1997

- Provided **primary care** pediatrics, inpatient and nursery hospital care
- Provided outpatient allergy and immunology **specialty care**
- **Supervised** nurse practitioner, office nurses, and receptionists
- Was the **first primary care pediatrics practice** dedicated to providing care to the **health-underserved** population in Sussex County, Delaware for the A. I. duPont Institute

Staff Allergist, Allergy–Immunology Service

David Grant USAF Medical Center
Travis AFB, CA 94535-5300

July 1991–July 1994

- Provided outpatient and inpatient allergy, asthma, and immunology **specialty care**
- Served active duty, dependents, and retirees in the Northern California area
- **Supervised allergy evaluations** performed by other providers at Western US and Pacific military sites
- **Supervised and trained** residents and primary care physicians in allergy
- **Supervised** allergy and immunization technicians

Pediatrician and Chief, Newborn Nursery

410th Strategic Hospital
K. I. Sawyer AFB, MI 49843

August 1987–June 1989

- Provided **primary care** general pediatrics, including inpatient hospital and nursery care
- Served active duty, dependents, and retirees in Northern Michigan
- **Supervised and trained** pediatrics and nursery nurses and technicians
- **Trained and supervised** family practice residents

Pediatrician

Dr. James J. Peipon and Associates
207-A Maryland Avenue
Salisbury, Maryland 21801

July 1986–July 1987

- Provided **primary care** general pediatrics, including inpatient hospital and nursery
- **Co-supervised and trained** pediatrics nurses and nursery nurses and technicians

Pediatrician, National Health Service Corps, USPHS

Broad Top Area Medical Center
Box 127

Broad Top, Pennsylvania 16621

July 1985–July 1986

- Provided **primary care** general pediatrics at a public clinic in a **health-underserved area**
- **PHS National Health Service Corps** service under the Private Practice Option

PREVIOUS PROFESSIONAL EXPERIENCE, continued

Pediatrician, National Health Service Corps, USPHS
Dickinson Medical Group, P.A.
800 North DuPont Highway
Milford, Delaware 19963
July 1983–April 1985

- Provided **primary care** general pediatrics including inpatient and outpatient pediatrics and nursery care in a **health-underserved area**
- **Trained and supervised** an office nurse
- **PHS National Health Service Corps** service under the Private Practice Option

ASSIMILATION

Appointed to Regular Corps
September 11, 2006

PRIOR MILITARY SERVICE

United States Air Force
Allergist-Immunologist, Pediatrician, Flight Surgeon
July 1987–July 1994, Honorable Discharge
Highest rank held: Lieutenant Colonel (O-5)

PRECEPT 4: PROFESSIONAL CONTRIBUTIONS TO THE PHS COMMISSIONED CORPS (OFFICERSHIP)

- Commissioned Corps Wind Ensemble, 2002-present
 - Participated in **biweekly rehearsals** and **62 performances**, including support at ceremonies for the Secretary and Assistant Secretaries of HHS, Surgeon General and Deputy Surgeon General and attended by Surgeons General of the Army and Air Force; awarded Special Assignment Award, Unit Commendation, and Surgeon General's Certificate of Appreciation for my participation
- PHS Commissioned Corps **lead and coordinator** for an amendment to the citations for two Navy and Marine Corps Meritorious Unit Commendations at NNMC. As a result of this action, **98 PHS officers** with duties at NNMC were awarded these decorations.
- Staff Physician, Allergy & Immunology, National Naval Medical Center, Bethesda, MD, as a professional development activity and to maintain clinical currency, 2001-present
- Provided guidance and encouragement resulting in the recruitment of 1 PHS officer and acted as informal mentor
- Peer reviewer for *Military Medicine*, 2002-present
 - **Reviewed** 10 manuscripts for scientific articles and provided **editorial comment**
- Member COA, AMSUS, ROA, 2001-present
- BOTC and IOTC completed, 2002
- Daily proud wear of uniform since 11 September 2001

PRECEPT 5: READINESS

- Basic level of OFRD **readiness maintained** since September 2003
- Assigned to **Tier 1** asset, Emergency Management Group Team A
- Deployment role: Primary Care Physician
- Deployed to Baton Rouge, LA from August 28 through September 9, 2005 in support of Hurricane Katrina relief efforts. One of the 37 PHS officers deployed with CAPT Charles McGarvey in the **initial PHS response to Hurricane Katrina**. Served as **Administrative Operations Officer** at the field hospital established at the Pete Maravich Assembly Center and **Lead Medical Officer** for 200-bed special needs facility during this deployment.
- Deployed in support of Presidential Inauguration, January 2005
- Completed all OFRD deployment readiness training modules required for the Intermediate and Advanced levels of deployment readiness
- Awarded Field Medical Readiness Badge, March 2007
- Completed four required FEMA Emergency Management Institute training courses
- Completed **advanced readiness training**:
 - Homeland Security Medical Executive Course, June 2006
 - Medical Effects of Ionizing Radiation Course, August 2004
- Medical History and Physical Examination current
- Participating in the President's Challenge fitness program, achieving 3 Presidential Champions Bronze Awards, 3 Presidential Champions Silver Awards, and 3 Presidential Champions Gold Awards; **95th percentile** among the 4974 USPHS participants
- Height and weight meet PHS standards
- Passed CCRF Annual Fitness Test at **Level 2**, 2006 and 2007

PUBLICATIONS, ABSTRACTS, PRESENTATIONS

PUBLICATIONS

Redacted.

Journal of Allergy and Clinical Immunology December 2007

Redacted.

Annals of Allergy November 1992

Redacted. Journal of Allergy and Clinical Immunology 89(5):1010-1020, May 1992.

Redacted. Molecular and General Genetics 1980.

ABSTRACTS

Redacted. Journal of Allergy and Clinical Immunology 1991.

Redacted. Journal of Allergy and Clinical Immunology 1991.

Redacted. Journal of Allergy and Clinical Immunology 1990.

PRESENTATIONS

Briefing for Pediatric Implementation Team regarding an applicant's Written Request for Pediatric studies for an inhaled bronchodilator for treatment of asthma, December 2007

Anaphylaxis associated with (drug name redacted)
Participated in briefing to CDER Director and CDER Senior Management Staff, Regulatory Briefing, January 2007

Briefing for Pediatric Implementation Team regarding an applicant's Written Request for Pediatric studies for an inhaled corticosteroid for treatment of asthma, January 2006

Briefing for Pediatric Implementation Team regarding an applicant's decision to decline a Written Request for Pediatric studies for an antihistamine used for the treatment of allergic rhinitis, August 2005

Testimony at deposition and trial as expert witness for FDA in case against Pharmakon, Inc., June 2005

Anaphylaxis in a new drug for the treatment of prostate cancer
Presentation to CDER Director and CDER Senior Management Staff, Regulatory Briefing, July 2003

Response to second Written Request for Pediatric Studies for (drug name redacted)
Presentation to Director, Office of New Drugs and Pediatric Exclusivity Board, January 2003

Over-the-counter indication for the treatment of hives for (drug name redacted)
Presentation for CDER Director of Medical Policy and ODE II Director, June 2002

Chronic obstructive pulmonary disease indication for (drug name redacted)
Presentation to Pulmonary-Allergy Drug Products Advisory Committee, January 2002

Response to first Written Request for Pediatric Studies for (drug name redacted)
Presentation to Pediatric Exclusivity Board, August 2000

Response to Written Request for Pediatric Studies for (drug name redacted)
Presentation to Director, Office of New Drugs and Pediatric Exclusivity Board, Regulatory Briefing, November 1999

Anaphylaxis in a new drug for the treatment of prostate cancer
Presentation to CDER Director and CDER Senior Management Staff, Pre-decisional Meeting, May 2001

Why is my asthma patient not getting better?
Fourth Annual David Grant USAF Medical Center Pediatric Update, Travis AFB, California, May 1992.

Interleukin-6 is released in the cutaneous response to antigen challenge.
Annual Scientific Session of the Association of Military Allergists, Fitzsimons Army Medical Center, Aurora, Colorado, February 1992.

Interleukin-6 is released in the cutaneous response to antigen challenge. Southwest Allergy Forum, San Antonio, TX, April 1991.
Second place award for abstract by a Fellow in Training.

Interleukin-6 is released in the cutaneous response to antigen challenge.
Poster presentation at the 47th Annual Meeting of the American Academy of Allergy and Immunology, San Francisco, California, March 1991.

Identification of peanut and true nut allergens.
Poster presentation at the 46th Annual Meeting of the American Academy of Allergy and Immunology, Baltimore, Maryland, March 1990.

Identification of peanut and true nut allergens.
Annual Scientific Session of the Association of Military Allergists, Fitzsimons Army Medical Center, Aurora, Colorado, February 1990.

Nucleoside transport in *Rickettsia typhi*.
Department of Microbiology, University of Maryland School of Medicine, Baltimore, Maryland, October 1977.

**NEW DRUG APPLICATION REVIEWS—FDA APPROVAL ACTIONS ONLY
(APPROVABLE AND NOT APPROVABLE ACTIONS NOT LISTED)**

Redacted.

Redacted.