

Curriculum Vitae

KARIM ANTON CALIS, PHARM.D, MPH, FASHP, FCCP

PERSONAL INFORMATION

Work Address: National Institutes of Health
Hatfield Clinical Research Center
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10 Center Drive (MSC 1109)
Bethesda, Maryland 20892
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EDUCATION

1995 Master of Public Health
Bloomberg School of Public Health
The Johns Hopkins University, Baltimore, MD

1986 Doctor of Pharmacy
School of Pharmacy
University of Maryland, Baltimore, MD

1984 Bachelor of Science in Pharmacy
School of Pharmacy
University of Maryland, Baltimore, MD

1979-1981 Pre-Pharmacy Studies
University of Maryland, College Park, MD

1979 Maryland High School Diploma
Robert E. Peary High School, Rockville, Maryland

BOARD CERTIFICATION & CREDENTIALING

Board Certified Pharmacotherapy Specialist (1992-1999)

Recertified (1999-2006)

BCPS Number 292219

Board of Pharmacy Specialties, Washington, DC

Board Certified Nutrition Support Pharmacist (1992-1999)

Recertified (1999-2006)

BCNSP Number 392256

Board of Pharmacy Specialties, Washington, DC

Credentialed in Core Patient Care Privileges (pharmaceutical care)

Supplemental credentials in Therapeutic Drug Monitoring (TDM), Parenteral Nutrition (PN), and Pain Management, 1999-2001

Credentialing Committee, NIH Clinical Center

Re-credentialed in Core Privileges, TDM, and PN, 2001-2003

Re-credentialed in Core Privileges, TDM, and PN, 2003-2005

Re-credentialed in Core Privileges, TDM, and PN, 2005-2007

Credentialing Committee, NIH Clinical Center

LICENSURE

State of Maryland Pharmacy License (1984-Present)

Maryland Board of Pharmacy, Baltimore, MD

License Number 10264

PROFESSIONAL EXPERIENCE

2017-Present

Director of Clinical Research and Compliance

Eunice Kennedy Shriver National Institute of Child Health and Human Development

National Institutes of Health, Bethesda, MD

2017-Present

Senior Scientist

Eunice Kennedy Shriver National Institute of Child Health and Human Development

National Institutes of Health, Bethesda, MD

2019-Present	Chair, NIH Institutional Review Board Office of Intramural Research National Institutes of Health, Bethesda, MD
2016-2019	Chair, NICHD Institutional Review Board <i>Eunice Kennedy Shriver</i> National Institute of Child Health and Human Development National Institutes of Health, Bethesda, MD
2014-2017	Senior Clinical Analyst Clinical Methodology Program Office of Medical Policy Center for Drug Evaluation and Research U.S. Food and Drug Administration
2016-2017	Acting Clinical Team Leader Division of Clinical Trial Quality Office of Medical Policy Center for Drug Evaluation and Research U.S. Food and Drug Administration
2012 (Jun-Sep)	Acting Clinical Team Leader Division of Metabolism and Endocrinology Products Office of New Drugs Center for Drug Evaluation and Research U.S. Food and Drug Administration
2009-2014	Clinical Reviewer Division of Metabolism and Endocrinology Products Office of New Drugs Center for Drug Evaluation and Research U.S. Food and Drug Administration
2012-2017	Adjunct Senior Clinical Investigator Office of the Clinical Director <i>Eunice Kennedy Shriver</i> National Institute of Child Health and Human Development National Institutes of Health, Bethesda, MD

- 2009-2012 Adjunct Senior Clinical Investigator
Program in Developmental Endocrinology and Genetics
Eunice Kennedy Shriver National Institute of Child Health and Human
Development
National Institutes of Health, Bethesda, MD
- 2009-2010 Adjunct Senior Clinical Investigator
Clinical Endocrinology Branch
National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health, Bethesda, MD
- 2007-2016 Vice Chair, Institutional Review Board
National Institute of Child Health and Human Development
National Institutes of Health, Bethesda, MD
- 1989-2009 Director, Drug Information Service
Mark O. Hatfield Clinical Research Center
National Institutes of Health, Bethesda, MD
- 1989-2009 Clinical Specialist, Endocrinology & Women's Health
Developmental Endocrinology Branch
Reproductive Medicine and Biology Branch
National Institute of Child Health and Human Development (NICHD)
National Institutes of Health, Bethesda, MD
- Metabolic Diseases Branch
Clinical Endocrinology Branch
Diabetes Branch
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
National Institutes of Health, Bethesda, MD
- NICHD/NIDDK Inter-institute Endocrine Service
- 1992-2002 Program Director
Specialized Residency in Drug Information Practice and
Pharmacotherapy (ASHP-accredited in Drug Information Practice)
Warren G. Magnuson Clinical Center
National Institutes of Health, Bethesda, MD

- 1988-1989 Assistant Director for Clinical Services
Department of Pharmacy
Suburban Hospital, Bethesda, MD
- 1987-1989 Director, Nutritional and Metabolic Support
Suburban Hospital, Bethesda, MD
- 1986-1988 Clinical Coordinator
Department of Pharmacy
Suburban Hospital, Bethesda, MD
- 1984-1986 Staff Pharmacist
Department of Pharmacy Services
Holy Cross Hospital, Silver Spring, MD
- 1984 Pharmacist
Gray Drug Fair (currently Rite Aid Pharmacy)
Potomac, Maryland
- 1980-1983 Pharmacy Extern
Peoples Drug Stores (currently CVS Pharmacy)
Rockville, Maryland

ACADEMIC APPOINTMENTS

- 2005-Present Clinical Professor
Department of Pharmacotherapy and Outcomes Science
School of Pharmacy, Medical College of Virginia
Virginia Commonwealth University, Richmond, VA
- 2003-Present Clinical Professor
Department of Pharmacy Practice and Science
School of Pharmacy
University of Maryland, Baltimore, MD
- 2003-2006 Clinical Professor
Department of Pharmacy, School of Pharmacy
Shenandoah University, Winchester, VA

- 2001-2009 Affiliate Faculty
Department of Pharmacy Practice
Idaho State University, Pocatello, ID
- 1998-2003 Clinical Associate Professor
Department of Pharmacy, School of Pharmacy
Shenandoah University, Winchester, VA
- 1998-2000 Adjunct Assistant Professor
Graduate School of Nursing
Uniformed Services University of the Health Sciences, Bethesda, MD
- 1996-2005 Associate Clinical Professor
Department of Pharmacy and Pharmaceutics, School of Pharmacy
Medical College of Virginia
Virginia Commonwealth University, Richmond, VA
- 1996-2003 Clinical Associate Professor
Department of Pharmacy Practice and Science, School of Pharmacy
University of Maryland, Baltimore, MD
- 1987-1996 Clinical Assistant Professor
Department of Pharmacy Practice and Science, School of Pharmacy
University of Maryland, Baltimore, MD

HONORS, AWARDS, & RECOGNITION

NIH Director's Award (Scientific/Medical Category), National Institutes of Health, June 2015 [Niemann-Pick Disease, type C Collaboration]

Certificate of Appreciation, Faculty for Pharmacy Student Experiential Program, Food and Drug Administration, May 215

NICHD Partnership Award, National Institute of Child Health and Human Development, December 2013 [The citation reads "For outstanding contributions to the NICHD Institutional Review Board"]

Group Recognition Award, Office of the Commissioner Honor Awards, FDA, August 2013

NIH Director's Award (Scientific/Medical Category), National Institutes of Health, June

2013 [Member of the Neimann-Pick Disease, type C Therapeutic Development Team]

Elected Member, Delta Omega National Honor Society in Public Health, May 2012
[In recognition of “distinguished scholarship and research in public health”]

George F. Archambault Career Achievement Award, U.S. Public Health Service, May 2010
[The citation reads “For exceptional career achievements in patient care, clinical research, and public health.”]

NIH Intramural Bench-to-Bedside Award (Women’s Health Category), 2008
Yanoff LB, Yanovski JA, Cropp C, Chen KY, Calis KA, Savastano D, Han JC, Barak N.
Histaminergic pathways and energy intake in obese women. [\$100,000/year for two years]

Andrew Craigie Award, Association of Military Surgeons of the United States (AMSUS),
August 2007 [The citation reads “For outstanding career contributions to clinical research and public health.”]

Allen J. Brands Clinical Pharmacist of the Year Award, U.S. Public Health Service, June 2007

Evander Frank Kelly Honored Alumnus Award, School of Pharmacy, University of Maryland, October 2005

Elected, Distinguished Practitioner, National Academies of Practice (DPNAP), July 2004

Award for Excellence in Clinical Pharmacy Practice, Association of Military Surgeons of the United States (AMSUS), August 2002 [The citation reads “For his excellence in clinical pharmacy practice, education, and research.”]

Elected, Fellow of the American College of Clinical Pharmacy (FCCP), September 2002

NIH Intramural Bench-to-Bedside Award, 2002
Parikh SJ, Zmmerberg J, Blank P, Adler-Wailes D, Feng N, Yanovski JA, McDuffie JR, Uwaifa GI, Sebring NG, Calis KA, Reynolds J. Intracellular calcium measurement in adipocytes: an adjunct to the study of supplemental calcium in overweight outpatients (SCOOP Study). [\$100,000/year for two years]

Pharmacy Practice Research Award [\$4,000]
ASHP Research and Education Foundation, 2001
Calis KA, Anderson DW, Auth DA, Mays DA, Turcasso NM, Meyer CC, Young LR.

Quality of pharmacotherapy consultations provided by drug information centers in the United States. *Pharmacotherapy* 2000 Jul;20(7):830-6.

Calis KA, Nelson LM, Pastor CL, Wesley RA, Tong ZB, Vanderhoof V, Bakalov V. FSH-stimulated inhibin B as a marker for early ovarian insufficiency. Ranked 2nd (not funded) in Women's Health Category, Research Institute Research Awards Program, American College of Clinical Pharmacy, 2001.

Visiting Professor [January 5-20, 2001], Japanese Ministry of Health and Welfare, Selected as part of a group of eight U.S. faculty members to educate Japanese clinicians about applied pharmacotherapy.

Certificate of Appreciation, Japanese Society of Hospital Pharmacists, Presented at Fukuoka University Hospital, Fukuoka, Japan, January 2001.

Certificate of Appreciation, Brazilian Society of Hospital Pharmacy, Salvador, Bahia, Brazil, November 8, 2000.

Elected, Fellow of the American Society of Health-System Pharmacists (FASHP), March 1996

Squibb Leadership Award (1993)

Mckesson Leadership Award (1993)

Hospital Pharmacist of the Year Award (1989)
Washington Metropolitan Society of Hospital Pharmacists

Elected, Outstanding Young Men of America, 1988

Recognition of Excellence (1984)
Pharmakon Editor, School of Pharmacy
University of Maryland, Baltimore, MD

Clinical Clerkships Completed with Honors (1984-1986): Ambulatory Care Medicine, Inpatient Medicine (3 different clerkships), and Clinical Research, School of Pharmacy University of Maryland, Baltimore, MD

PROFESSIONAL AFFILIATIONS

American College of Clinical Pharmacy

Women's Health Practice and Research Network (PRN)

Drug Information Practice and Research Network (PRN)

Endocrine and Metabolism (PRN)

American Diabetes Association

Professional Section

American Pharmaceutical Association

American Society for Parenteral and Enteral Nutrition

Research Section

American Society of Health-System Pharmacists

Section of Clinical Specialists

Drug Information Specialty Practice Group (SPG)

Nutrition Support Specialty Practice Group (SPG)

Association of Military Surgeons of the United States

Chesapeake College of Clinical Pharmacy

Drug Information Association

International Society for Pharmacoepidemiology

Kappa Psi Pharmaceutical Fraternity

League of Intravenous Therapy Education

Maryland Society for Parenteral and Enteral Nutrition

Maryland Society of Health-System Pharmacists

National Academies of Practice

Society for Epidemiologic Research

The Cochrane Collaboration

Gynaecology and Fertility Group (formerly the Menstrual Disorders & Subfertility Group)

The Endocrine Society

University of Maryland Alumni Association

Washington Metropolitan Society of Health-System Pharmacists

PROFESSIONAL ACTIVITIES & APPOINTMENTS

Department of Health and Human Services

Member, Advisory Committee on Development of Hypoglycemia eLearning Tool, Office of Disease Prevention and Health Promotion (ODPHP), 2013-2014

Food and Drug Administration

Member, Drug Safety and Risk Management Advisory Committee, 2019 to Present

Panelist, Part 15 Public Hearing, Confidentiality of Interim Results in Cardiovascular Outcome Safety Trials, August 11, 2014

Project Team Leader, Data Monitoring Committees, Clinical Trials Transformation Initiative, Duke University, June 2014-Present

Bisphenol A (BPA) Joint Emerging Science Working Group, Office of the Commissioner, 2013-2014

DMEP Representative, Visiting Professor Lecture Series (VPLS), 2009 to 2014

External Reviewer, Regulatory Science and Review Enhancement (RSR), 2010

Member, CDER Committee for Advanced Scientific Education (CASE), 2011 to 2014

Member, Seminar Subcommittee (July 2011 to June 2012 and June 2013 to June 2014)

Member, Abrams Award Working Group (2012)

Member, Curriculum Subcommittee (July 2012 to June 2013)

Chair, Abrams Award Working Group (2013)

Cardiovascular Endocrine Liaison Program (CELP), Breakout Session, Second Annual Health Professional Organizations Conference, October 4, 2012, FDA White Oak Campus, Silver Spring, Maryland

Presentation to the Endocrinologic and Metabolic Drugs Advisory Committee, Clinical Safety of Insulin Degludec and Insulin Degludec/Insulin Aspart, November 8, 2012

Consultant, Drug Safety and Risk Management Advisory Committee, Center for Drug Evaluation and Research, Food and Drug Administration, 2007-2009

National Institutes of Health

NICHD BPCA Work Group, 2018 to Present

NICHD Strategic Planning Working Team, 2018 to Present

Literature Selection Technical Review Committee, National Library of Medicine, 2013-2014

Member, Data and Safety Monitoring Committee, National Institute of Child Health and Human Development — Intrathecal 2-Hydroxypropyl- β -Cyclodextrin in Patients with Niemann-Pick Type C1 Disease [13-CH-0001], 2012-Present.

Chair, Data and Safety Monitoring Board, National Institute of Child Health and Human Development — The safety and effectiveness of surgery with or without raloxifene for the treatment of pelvic pain caused by endometriosis [Protocol 99-CH-0012], 1999-2002.

Member, Data and Safety Monitoring Board, National Institute of Arthritis and Musculoskeletal and Skin Diseases — A randomized, third party-blind, placebo-controlled pilot study of the effects of h5G1.1-mAb on dermatomyositis patients [Protocol 00-AR-0117], 2000.

Member, Data and Safety Monitoring Board, Craniofacial & Skeletal Diseases Branch, Division of Intramural Research, National Institute of Dental and Craniofacial Research — A randomized, placebo-controlled study of alendronate in the treatment of polyostotic fibrous dysplasia of bone and the McCune-Albright Syndrome [Protocol 98-D-0146], 1999-2001.

Ad Hoc Member, NICHD Data Safety Monitoring Committee, National Institute of Child Health and Human Development, 2002-2009.

Preceptor, Drug Information and Pharmacotherapy, Pharmacy Practice Residency (ASHP-accredited program), Department of Pharmacy, Warren G. Magnuson Clinical Center, National Institutes of Health, Bethesda, MD, 1989-2001.

Co-Chair, Publication and Data Analysis Committee, National Institute of Mental Health — Prevalence of low bone mass and effect of alendronate on bone loss in premenopausal depressed women (The POWER Study) [Protocol 00-M-0203], 2002-2005

Member, Pharmacy and Therapeutics Committee, 1990-2009

Chair, Cytokines Subcommittee, 1991-1996

Chair, Antimicrobials Subcommittee, 1990-2009

Member, Drug Utilization Evaluation Subcommittee

Co-Chair, Drug-Nutrient Interactions Task Force, 1997-2009

Chair, Parenteral Nutrition Task Force, 2001-2002

Antifungals Task Force, 2001

Endocrine/Rheumatology Task Force, 2001

Co-Chair, Nutrition Support Committee, 2002-2004

Member, Scientific Committee, The Menstrual Cycle and Bone Health (Community for Building Healthy Bones), National Institute of Child Health and Human Development, 2002-2009

Symposium Organizing Committee, 1999-2000

The ovary: genesis, function, and failure, Natcher Building and Conference Center, March 30-31, 2000.

Working Group on Pharmacology in Aging and Cancer, National Institute on Aging (NIA), National Cancer Institute (NCI), and Agency for Health Care Policy Research (AHCPR), December 2, 1994.

Member, Institutional Review Board, National Institute of Child Health and Human Development, 1989-Present

Alternate Member, Institutional Review Board, National Institute of Dental Research, 1992-1994

Coordinator, Pharmacy Journal Club

Pharmacology/Toxicology Subcommittee,
Interagency Animal Model Committee, DHHS, 1990-2005

Editor, *Pharmacy Update*

Intravenous Therapy Task Force, 1992-1994

Administrator, Continuing Education Program, (approved by the Accreditation Council on Pharmacy Education), 1990-2007.

Suburban Hospital, Bethesda, MD

Instructor, Diabetes Education Program (ADA-recognized program), 1986-1989

Pharmacy & Therapeutics Committee, 1986-1989

Nutrition Committee, 1986 - 1989

Infection Control Committee, 1986 – 1989

Editor, *Pharmacy Update*

Department of Pharmacy Newsletter, 1986-1989

Hospital Speakers' Bureau, 1987-1989

University of Maryland, Baltimore, MD

Coursemaster, Principles of Drug Literature Evaluation (PHNT 506)

Spring 1996 and Spring 1997

Preceptor for introduction to clinical practice, drug information, and internal medicine
clinical clerkships for doctor of pharmacy students, 1987 - 2009

Educational Advisory Committee, 2005-2009

Chairman, Educational Advisory Committee, 1999-2001

Educational Advisory Committee, 1998–1999

Guest Lecturer, Medical Information Analysis (PHAR 550), 1994-2001.

Founding Editor, *Pharmakon* (1983), School of Pharmacy

University of Maryland, Baltimore, MD

American Society of Health-System Pharmacists, Bethesda, MD

Drug Information SPG

Research Forum Review Committee

Strategic Planning Committee

Member, Council on Administrative Affairs, 1994-1995

Contributed Papers Review Panel, Midyear and Annual Meetings, 1988-

Meeting Programming Associate/Educational Programming Associate

Team Member and Reviewer, ASHP Clinical Skills Program: Drug Information Series 1993-1994

Member, Committee on Public Policy and Government Relations, Section of Clinical Specialists, 1995

Residency Accreditation Survey Team
Texas Tech University
University of Pittsburgh

Reviewer—Fluids, Electrolytes, and Nutrition Section
Ginsburg DB. ASHP's PharmPrep. Bethesda: American Society of Health-System Pharmacists, 2001.

Reviewer—ASHP Therapeutic Position Statement on the Safe Use of Pharmacotherapy for Obesity Management in Adults. *Am J Health-Syst Pharm* 2001; 58:1645-55.

Washington Metropolitan Society of Health-System Pharmacists
President (1992-1993)

Chair, Board of Directors (1992-1993)

Programs Committee (1988)

Chairman, Research and Education Committee (1987 - 1990)

American College of Clinical Pharmacy, Kansas City, MO
Chair, Public and Professional Affairs Committee (2001-2002)

Chair-Elect, Women's Health PRN (2001-2002)

Chair, Women's Health PRN (2002-2003)

Abstract Reviewer (1997-2009)

Credentials Committee, 2000-2001

Research Affairs Committee B, 1999-2000

Board Certification Affairs Committee, 1998-1999

Research Affairs Committee, 1997-1998

Spring Research and Practice Forum Program Committee, 1997

Moderator, Updates in Pharmacotherapy – Innovative Therapeutics, 1997

Focus Group Participant, Spring Forum, April 7, 1997

The United States Pharmacopeial Convention

Executive Committee of the Council of Experts, 2007-2009

Chair, Endocrinology Expert Committee, 2005-2009

Council of Experts, 2005-2009

Vice Chair, Medicare Model Guidelines Expert Committee, 2005-2009

Medicare Model Guidelines Expert Committee, April 2004-2009

Nutrition and Electrolytes Expert Advisory Panel, 1995-2000.

Endocrinology Expert Committee, 2000-2005

Contributor, *United States Pharmacopeia Dispensing Information (USP DI)*, 1988 - 2004

Other Organizations

Member, Women's Health Curriculum Task Force

American Association of Colleges of Pharmacy and FDA Office of Women's Health, 2010

Expert Panel, Improving the Use and Safety of Medications in Women Through Gender and Race Analysis, Agency for Healthcare Research and Quality (AHRQ), April 19-20, 2004.

Pharmaceutical Care Subcommittee, Pharmacy Professional Advisory Committee, United States Public Health Service, 2001-2002

Scientific Program Committee, International Conference on Pharmacoepidemiology, International Society for Pharmacoepidemiology, 1995-

Clinical Consultant (2004-2005)
Caremark, Inc., Nashville, Tennessee

Pharmacy and Therapeutics Committee (2001-2004)
External Review Committee (2003-2005)
AdvancePCS, Minneapolis, MN

Medical and Pharmacy Advisory Board (1997-2001)
Advance Paradigm, Baltimore, MD

Consultant, "Rx-to-OTC Switch" Project, College of Pharmacy, 1996-1997
University of Tennessee, Memphis, TN

Editorial Advisory Board (emergency medicine medical informatics system), Cybermedix,
Inc., Springfield, VA, 1988-1995

Council of Pharmacists, *Drug Topics*, 1988 - 2009

Research Committee, Holy Cross Hospital, Silver Spring, MD, 1993-1999

Clinical Reviewer and Consultant, Health Information Designs, Inc., Arlington, VA, 1987 –
199X

Site Coordinator and Participant, Drug Surveillance Network, Center for
Pharmacoepidemiology Research, State University of New York, Buffalo, NY
1989 - 1996

Member, Mid Atlantic Pharmacy Cholesterol Council
National Pharmacy Cholesterol Council

Field Reviewer, Continuing Pharmacy Education Programs
American Council on Pharmaceutical Education

External Reviewer, Tenure and Promotions
University of Maryland (Drs. David Mays and Magaly Rodriguez de Bittner)
Howard University (Dr. Joseph Ofosu)
Medical University of South Carolina (Dr. Nannette Berensen)
St. John's University (Dr. Priti Patel)

Community Service

Volunteer (#0226), Medical Reserve Corps, Office of the County Executive, Montgomery County, Maryland, 2005-Present

Member, Parish Council, 2011-2014

Saint John the Baptist Catholic Community

Silver Spring, Maryland

Reviewer

Acta Paediatrica

American Hospital Formulary Service, ASHP

American Journal of Health-System Pharmacy

Annals of Pharmacotherapy

Annals of Internal Medicine

Archives of Internal Medicine

Biopharmaceutics and Drug Disposition

Hospital Formulary

Hospital Pharmacy

Journal of Clinical Endocrinology and Metabolism

Journal of Natural Products

Journal of Parenteral and Enteral Nutrition

Journal of the American Medical Association

Journal of the American Pharmacists Association

Nonprescription Drug Therapy: Guiding Patient Self-Care, Facts & Comparisons

Pharmacology for the Primary Care Provider, Mosby

Pharmacotherapy

The Journal of Alternative and Complementary Medicine

The New England Journal of Medicine

United States Pharmacopeia Dispensing Information (USP DI), USP

Editorial Advisory Boards

2008-2009 *The Open Drug Safety Journal*, Bentham Science Publishers

2007-2009 *Annals of Pharmacotherapy*
Women's Health Editorial Panel

2005-2008 *Journal of Parenteral and Enteral Nutrition*

2002-2009 *Hospital Pharmacy*

- 2000-2003 *The Journal of Alternative and Complementary Medicine*
- 2000-2002 *DrugInfoLine*, American Pharmaceutical Association
Endocrinologic Disorders Section Advisor
- 2000-2001 *DrugInfoLine*, American Pharmaceutical Association
Diabetes Care Section Advisor
- 2001-2004 *Journal of the American Pharmaceutical Association*
- 1993-2009 *DRUGDEX System*, Micromedex, Inc.
Assistant Editor
- 1995-1998 *American Journal of Health-System Pharmacy*

TEACHING EXPERIENCE

Didactic teaching (guest lecturer) for the University of Maryland and Shenandoah University

Experiential teaching for the University of Maryland, Howard University, Shenandoah University, Virginia Commonwealth University, and others

Guest lecturer in the following nursing pharmacology courses:

- Nurse Practitioner Program, Uniformed Services University of the Health Sciences, Bethesda, MD
- Undergraduate Nursing, Catholic University of America, Washington, D.C.

Clinical analysis of adverse drug reactions, Principles of Clinical Pharmacology Course, Clinical Pharmacology Research Associate Training Program, Warren G. Magnuson Clinical Center, National Institutes of Health; March 18, 1999, March 16, 2000, March 8, 2001, March 7, 2002.

Program Director for the Specialized Residency in Drug Information Practice and Pharmacotherapy.

RESEARCH EXPERIENCE

Principal Investigator

A pilot study of cimetidine-aided creatinine clearance to assess glomerular filtration rate in children, 96-CC-0042

A comparison of chloral hydrate and orally administered midazolam for sedation of pediatric patients undergoing diagnostic imaging procedures (*Study was approved but not initiated because of limited resources*)

Evaluation of the quality of pharmacotherapy consultations provided by U.S. drug information centers (*NIH OHSR deemed this study exempt from IRB consideration*)

Associate or Co-Investigator

An open-label phase 3 study of the safety and efficacy of pegvisomant in children with growth hormone excess

Biomarker validation for Neimann-Pick disease, type C: safety and efficacy of n-acetyl cysteine

A pilot study to assess the feasibility of PTH-1-34 therapy via pump in the management of chronic hypoparathyroidism, 08-CH-0203

A Phase II open-label, crossover pharmacokinetic and pharmacodynamic study to compare Chronocort versus Cortef in patients with congenital adrenal hyperplasia

A pilot study evaluating the feasibility of using human parathyroid hormone (1-34) eluting poly(lactic-co-glycolic acid) microspheres for treatment of hypoparathyroidism

Pilot study of the metabolic effects of betahistine hydrochloride in overweight women

Physiologic regulation of fibroblast growth factor-23 (FGF-23), 06-NIDCR-XX

Effect of transdermal estradiol replacement therapy on ovulation rates in women with premature ovarian failure: a randomized, placebo-controlled trial, 06-CH-0201

The role of the orexin system in body weight regulation: patients with narcolepsy, 06-DK-0079

Chronic sleep deprivation as a risk factor for metabolic syndrome and obesity, 06-DK-0036

The effects of hydrocortisone, melatonin, and placebo on symptoms of jet lag, 05-CH-0037

Investigation of simvastatin therapy in Smith-Lemli-Opitz syndrome, 03-CH-0225

Study of thyrotropin releasing hormone in normal volunteers and in patients with thyroid or pituitary abnormalities, 03-DK-0098

Supplemental calcium in overweight outpatients (SCOOP Study), 02-CH-0100

Heparin vs. lepirudin flushes in preventing withdrawal occlusion of tunneled, open-ended venous access devices: a blinded, randomized, clinical trial, 02-CC-0203

Assessment of pre- and post-synaptic dopamine function in developmental stuttering using ^{11}C raclopride and positron emission tomography, 02-DC-0008

Turner Syndrome: hormone replacement therapy, 01-CH-0114

FSH-stimulated inhibin B as a marker for early ovarian insufficiency, 00-CH-0189

The P.O.W.E.R. Study (Premenopause, Osteopenia/ Osteoporosis, Women, Alendronate, Depression): prevalence of low bone mass and effect of alendronate on bone loss in premenopausal depressed women, 00-M-0203

A pilot study of the effects of the aromatase inhibitor letrozole on indices of bone turnover in girls with precocious puberty due to the McCune-Albright Syndrome (*includes a pharmacokinetics study amendment*), 00-D-0183

Hormone replacement in young women with premature ovarian failure (*controlled trial of TMTDS testosterone patch*), 00-CH-0045

Efficacy of leptin replacement in the treatment of lipodystrophy, 00-DK-0146

Effects of metformin on energy intake, energy expenditure, and body weight in overweight children with insulin resistance, 00-CH-0134

Safety and efficacy of orlistat in African American and Caucasian children and adolescents with obesity-related co-morbid conditions, 98-CH-0111

Transdermal androgen replacement therapy for young women with spontaneous premature ovarian failure: a pilot study, 98-CH-0045

The use of metformin to improve fertility in clomiphene-resistant hyperandrogenic anovulation: a double-blinded, placebo-controlled study, 98-CH-0050

Investigation of the human immune response in normal subjects and patients with disorders of the immune system and cancer, 97-C-0143

Effect of diltiazem on renal function in cyclosporine-treated uveitic patients, 97-EI-0179

Genetic linkage analysis in developmental stuttering: gene mapping in extended kindreds and candidate gene studies, 97-DC-0002

Efficacy of long-term thiazolidinedione therapy in syndromes of severe insulin resistance and lipodystrophy, 97-DK-0203

Ovulation induction in patients with karyotypically normal spontaneous premature ovarian failure

Fadrozole treatment of women to induce formation of multiple preovulatory follicles.

Development of an infusible serum-free medium to support or expand human cells used in gene therapy trials, 1997 (*In vitro, Exempt*)

Efficacy of rosiglitazone or pioglitazone in treatment of lipodystrophy syndrome and nonalcoholic steatohepatitis, 97-DK-0203

Use of advanced nuclear medicine imaging techniques to evaluate drug toxicity in a murine model, 1996 (*Animal, Exempt*)

Cyclodextrin itraconazole in the treatment of oropharyngeal candidiasis in children with HIV infection, 96-C-0041

Use of flutamide in clomiphene-resistant anovulation, 96-CH-0114

An open, randomized, long-term clinical trial of flutamide, testolactone (amendment approved to replace testolactone with letrozole), and reduced hydrocortisone dose vs. conventional treatment of children with congenital adrenal hyperplasia, 96-CH-0033

Treatment trial of oral immunoglobulin in a patient with common variable hypogammaglobulinemia and inflammatory bowel disease, 96-C-0135

Childhood-onset schizophrenia: characterization and treatment with typical and atypical neuroleptics, 96-M-0025

Amphotericin B lipid complex in the treatment of severe mucocutaneous candidiasis: a pilot study, 1995 (*Study was approved but not initiated*)

Regional cerebral blood flow autoregulation in hypertensive cerebrovasculopathy: the efficacy of pharmacological intervention, 95-AG-0022

Childhood onset schizophrenia: an open trial with the atypical neuroleptic olanzapine, 95-M-0170

A double-blind trial of pimozide and paroxetine following clomipramine treatment in persons who stutter, 94-DC-0210

Evaluation of 5-fluorouracil-induced cardiotoxicity, 1994 (*Exempt*)

A double-blind, randomized trial of low molecular weight heparin (enoxaparin) to prevent thrombosis related to venous access devices, 94-CC-0136

Low-dose continuous infusions of urokinase with or without heparin to treat fibrinous occlusion of tunneled venous access devices: a randomized, double-blind study, 93-CC-0135

Hydroxychloroquine pharmacokinetics in a patient with systemic lupus erythematosus undergoing continuous ambulatory peritoneal dialysis, 1993 (*Exempt*)

Autoimmune premature ovarian failure: a controlled trial of alternate-day prednisone therapy, 92-CH-0223

Ovarian follicle function in patients with premature ovarian failure, 91-CH-0127

Evaluation of the clinical utility of a computerized, patient-driven medication history in the detection and management of adverse drug effects, 1990 (*Exempt*)

IND Applications (co-investigator):

Antalarmin (pending)
N-Acetyl Cysteine for Neimann-Pick Disease Type C
Human parathyroid hormone (two separate INDs)
TMTDS testosterone patch for women (IND 60,587)
Lepirudin for maintenance of catheter patency
Leptin for lipodystrophy
Orlistat for childhood obesity
Metformin for childhood obesity and insulin resistance
Flutamide for ovulation induction in women with PCOS
Letrozole for girls with precocious puberty (IND 60,057)
Simvastatin (oral suspension) in Smith-Lemli-Opitz Syndrome
Thyrotropin releasing hormone (NIH formulation)

BOOKS & BOOK CHAPTERS

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ABSTRACTS

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