CURRICULUM VITAE

Contact Information:

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Georgetown University, Associate Professor of Pharmacology:

July 2010 - CURRENT

- Associate Professor, lecturer and thesis advisor to graduate level pharmacology and medical students in various therapeutic areas.
- Research advisor for Medical and Pharmacology Ph.D. students.
- See website at Georgetown University for details.

Journal Editorial Boards:

Journal of Pharmacology & Clinical Toxicology: 2012 – CURRENT
Journal of Drug Research and Development: 2013 – CURRENT

- Editor for submitted articles on the topics of: investigational medicine, adverse events and case reports in the area of clinical pharmacology, drug-induced QT prolongation, cardiovascular pharmacology, pharmacokinetics and dynamics, drug delivery and metabolism, pharmacology of the vascular and central nervous system, et cetera.

US Food and Drug Administration, (FDA) Medical Officer/ Senior Analyst:

December 2007 – December 2010
Division of Metabolism and Endocrinology Products (DEMP)
Office of Drug Evaluation, Office of New Drugs.

- Lead reviewer responsible for various safety and efficacy analyses of clinical study proposals, reports, product labeling BLAs, NDAs, INDs, new protocols and protocol amendments.
- Lead medical officer for the *SEARCH* trial: "Study of the Effectiveness of Additional Reductions in Cholesterol and Homocysteine" addressing the safety and efficacy of simvastatin 80mg.
- Lead efficacy medical officer for the Livalo (pitavastatin) NDA.
- Prepared written summaries and formal presentations of safety and efficacy of protocols and package labeling for interdisciplinary reviewers and division directors.
- Advised sponsors on the suitability of drug development plans and clinical trials were adequate and well-controlled, and sufficient to support the efficacy and safety of drugs under investigation, based on the available data.

- Reviewed post-marketing safety reports, databases and safety submissions to determine if there were potential issues that required further evaluation or product labeling changes.
- Provided advice and direction to pharmaceutical sponsors and investigators on the design of clinical studies.
- Compiled data to prepare special reports related to the work of the Division and analyzed background data pertinent to FDA programs.
- Assessed New Drug Applications, supplements and pre-clinical applications based on the most recent version of FDA guidance documents and The Code of Federal Regulations.

Yale University, Assistant Professor of Pharmacology:

January 2004 – January 2008:

Assistant Professor (Timothy Dwight College Fellow, Chubb Fellow)
Department of Pharmacology,
Yale School of Medicine

- Lectured on graduate level clinical pharmacology for medical, physician assistant and pharmacology Ph.D. students. Lectures and discussions include cardiology, metabolic diseases, obesity, alcohol pharmacology/neuropharmacology, drug development, drugs of abuse, among others.
- Research advisor for Medical, Physician Assistant and Pharmacology Ph.D. students. Thesis committees and participation in rotation guidance.
- Clinical investigation analyzing and standardizing drug therapy during surgical procedures including carotid endarterectomy and carotid stenting procedures.
- Clinical investigation on compounds which have the potential to modulate endogenous cholesterol levels.
- Basic science research exploring various hemodynamic cell signaling pathways related to vascular wall thickening, inflammation, plaque stabilization, migration and the non-random localization of atherosclerotic plaques in the vasculature.
- Faculty member of the Yale University Center for Bioethics, Research Ethics working group and Research Ethics writing group.
- Involved in multiple interdisciplinary scientific and research collaborations as well as various academic presentations to the faculty.

Pharmaceutical Industry: Merck Inc. Vioxx Litigation Consultant and Expert Witness:

January 2005 - December 2007

Expert witness and consultant on the clinical use of drugs and basic science pharmacology Williams and Connolly LLP and Fulbright & Jaworski LLP

- Applied expertise to research, consult and deliver expert witness services to litigators defending Merck Inc. in Vioxx litigation.

- Used clinical pharmacology and basic science research to give a comprehensive interpretation of scientific publications related to vascular occlusion and thrombosis.
- Performed an independent and comprehensive search and examination of the medical literature as pertaining to the defendant's case.
- Communicated directly with publication authors on studies as necessary to clarify detail and endpoints.
- Provided independent opinion in a detailed and heavily referenced publication-style report.
- Provided additional reports in an easy to understand format for the expert as well as the lay individual.

Pfizer Inc., Investigational Medicine Scientist

November 2001 - December 2004
Investigational Medicine Research Scientist
Clinical Research and Development,
Pfizer Inc., Groton/ New London, CT

- Responsible for designing, implementing and driving the process of state-of-the-art clinical pharmacology studies for multiple early and full development compounds.
- Designed and composed Phase 1 and 2 protocols and study reports for first-in-human studies, multiple dose studies, food effect studies, dose escalation studies, drug interaction studies and dose bioequivalence studies.
- CRO negotiations, supervision and management
- Responsible for study implementation including:
  - Chairing study team meetings
  - Managing a multidisciplinary operational group: (clinical research associate, project assistant, medical monitor, assay coordinator, biometrician, data manager)
  - CRO selection, study initiation, clinical safety monitoring
  - Projecting study budgets and recognizing/ implementing areas of cost savings in study design and conduct.
- Contributor to Early Clinical Development Plans of early phase compounds
- Ad hoc presenter of various clinical, scientific and protocol related topics.

Postdoctoral Training: Yale University Vascular Medicine/ Pharmacology Fellowship:

December 1999-January 2002:
Vascular and Cardiovascular Medicine Postdoctoral Fellowship
Department of Surgery, Section of Vascular Surgery,
Yale School of Medicine

- Basic Science research related clinically to cholesterol, arteriosclerosis, intimal hyperplasia, diabetes and hypertension.
- Clinical Research: Coordinator for multiple clinical trials assessing efficacy in atherosclerosis and hypertension. Responsible for GCP adherence. Screened and managed patients or subjects in studies.

Basic Science Pharmacology Research Fellowship, Yale University (Laboratory activities):

December 1999 to January 2002:

Vascular and Cardiovascular Medicine Research Fellowship, Yale School of Medicine

- Studied the effect of atherosclerosis, diabetic levels of glucose isomers, and their effects on endothelial and smooth muscle cells.
- Red wine polyphenols, (with emphasis on resveretrol and quercetin) and their role in atherosclerotic disease. Studied smooth muscle migration and cell cycle analysis as related to atheroma formation.
- Cyclic strain induced activation of pro-survival cascades in bovine aortic endothelial cells and bovine aortic smooth muscle cells.
  - The effects of cyclic strain on the phosphorylation of AKT and BAD in vascular endothelial and smooth muscle cells.
  - The effects of cyclic strain on the rate and extent of apoptosis in vascular endothelial and smooth muscle cells.
  - The effects of cyclic strain on transcription factor NF[k]B in vascular endothelial and smooth muscle cells.
- The significance of cytoskeleton integrity in mechanical stress induced signal transduction in bovine aortic endothelial cells.
  - Cyclic strain induced activation of the GTPase RhoA.
  - The effects of cytochalasin B on cyclic strain induced activation of MAPK.
- The effects of galvanotaxis on vascular endothelial and smooth muscle cells.

Yale University Fellowship, Clinical Research Activities (Continued):

Vascular and Cardiovascular Medicine Research Fellowship, Yale School of Medicine

- Clinical research investigator/coordinator in charge of screening patients upon verification of diagnosis.
- Applied GCP standards for all patient follow-up and monitoring of safety and efficacy parameters.
- Served as the primary or secondary contact at Yale University for listed investigational drug trials.
- Responsible for protocol adherence, study drug accountability, compliance assessment, and adverse event assessment.
- Responsible for regulating compliance with investigational compound sponsor and the University Human Investigation Committee.
- Designed and conducted research projects exploring the molecular mechanisms of hypertension and diabetes in association with cholesterol

plaque formation and intimal hyperplasia as related to hemodynamics.

- Worked under an annually renewed NIH (RO1 HL 47345-05) and VA Merit Review Grant.

Postdoctoral Training: Specialty Residency: Yale-New Haven Hospital:

July 1999-January 2000:

Clinical and Investigational Drug Information Residency (ASHP Accredited)
The Yale-New Haven Hospital. New Haven, CT

- Performed extensive literature research on complex questions regarding drugs and pharmacotherapy.
- Worked with the Yale University Investigational Drug Service on managing the approximately 200+ drug trials at Yale University.
- Responsible for providing Yale physicians with information on medication use (drug-drug interactions, pharmacologic mechanism, unapproved uses, et cetera)

Postdoctoral Training: General Residency: Columbia Presbyterian

July 1998 to July 1999

General Clinical Pharmacy Practice Residency (ASHP Accredited)
The Valley Hospital (affiliate of Columbia Presbyterian Medical Center)
Ridgewood, NJ

- Special emphasis in cardiac and psychiatric pharmacology
- Pharmacy and Therapeutics Committee member (addressing disease state management protocol and hospital formulary issues)
- Investigational New Drug Review Committee member. Worked with private industry to set up clinical trials in several patient populations.
- Anticoagulation and Hypertension clinic team member.
- Twice-weekly clinic and patient assessment with appropriate dosage and lifestyle recommendations.
- Residency project: "Standardizing Hyperlipidemia Treatment in Postoperative Cardiac Patients." Meta-analysis cohort funded with a grant from Merck Pharmaceuticals.

Assistant Clinical Instructor, Department of Pharmacy Practice,
Rutgers College of Pharmacy, Piscataway, NJ

Assistant Clinical Instructor, Bergen Community College,
Department of Nursing, Paramus, NJ

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