LAWRENCE J. LESKO, PH.D., F.C.P.
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EMPLOYMENT

2011 – Present
Professor and Director
Center for Pharmacometrics and Systems Pharmacology
Department of Pharmaceutics
College of Pharmacy
University of Florida,
Orlando (Lake Nona), Florida

1995 – 2011
Director, Office of Clinical Pharmacology (OCP)
Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA), Rockville, Maryland

- Responsible for directing the overall development and management of the review, policy and research components of the clinical pharmacology and biopharmaceutics program in CDER-FDA
- Provide office level oversight of scientific review packages for selected IND's and all original NDA's
- Provide overall direction and management of CDER's Interdisciplinary Pharmacogenomics Review Team and Pharmacogenomics Program
- Provide initiation and direction for critical path programs in clinical pharmacology including model-based drug development, biomarker qualification, EOP2A meetings and individualization of therapy
- Responsible for Leadership Training and Development in OCP as part of the OCP "Good to Great" initiative from 2003 to 2010
- Responsible for the recruitment of high quality scientists and retention of scientific staff; building leadership throughout the organization through structured skill set programming
- Responsible for innovations in regulatory review such as the Question Based Review, NDA regulatory briefings and Scoping Meetings for new NDAs to pinpoint major review issues for industry and drug development
- Responsible for Clinical Pharmacology Advisory Committee and leading of label changes to include pharmacogenetic information
- Organize annual PhRMA (BIO)-FDA-OCP meetings to discuss contemporary topics in drug development and regulatory science
- Lead the development of guidances in clinical pharmacogenomics, special populations (renal and hepatic impairment), pediatrics,

population PK and exposure-response relationships that define a framework for contemporary drug development
- Member of CDER's Drug Safety Oversight Board responsible for oversight of CDER safety and policy decisions
- Chair of FDA's Pharmacogenomics Working Group responsible for guidance development, policy development and overall leadership of the intercenter genomics initiative
- Chair of CDER's Medical Policy Coordinating Committee- Clinical Pharmacology Section responsible for the development and implementation of clinical pharmacology guidances for industry
- Represented FDA on the ICH Common Technical Document Working Group from 2000-2003 (M4)
- Lead representative from FDA on the ICH Pharmacogenomics Working Group (E15) from 2006-2008
- Consultant to the American College of Medical Genetics on the pharmacogenetics of warfarin guidelines (2007)
- Represented FDA on the OECD initiative on Pharmacogenomic (2006)

1992 - 1995 Associate Director of Research, Office of Generic Drugs (OGD), CDER, FDA, Rockville, Maryland

- CDER's Project Officer for all extramural research contracts including those in formulations and biopharmaceutics research that formed the basis for the SUPAC-IR and SUPAC-MR guidances for industry, and the solubility/permeability research that underpinned the Biopharmaceutics Classification System and food effects guidances for industry.
- Supervise and manage short-term review-related regulatory research in the Generic Drug Research Laboratory
- Office-level secondary assessment of bioequivalence study reviews in all ANDAs prior to approval
- Consultant to various offices in CDER on complex formulation and biopharmaceutical issues arising from new and generic drug development
- Organize and manage agendas, speakers and Generic Drug Advisory Committee meetings dealing with biopharmaceutics issues
- Development of general and drug-specific bioequivalence guidances for industry

1988 - 1992 Chief Scientific Officer and Vice-President
Analytical Laboratory Services Division
PharmaKinetics Laboratories
Baltimore, Maryland

- Top-level review of all analytical, pharmacokinetic and clinical study designs, data analysis and final study reports
- Development and validation of new bioanalytical methods.
- Implementation of an a new in vitro dissolution service
- Strategic planning and business plan development
- New business development in pharmaceutical industry

1981 - 1988 Associate Professor of Pharmaceutics and Director, Clinical Pharmacokinetics Laboratory, University of Maryland at Baltimore (UMAB), School of Pharmacy, Baltimore, Maryland

- Responsible for the clinical pharmacology and biopharmaceutics graduate research program, and extramural contracts with pharmaceutical sponsors
- Director of a therapeutic drug monitoring service at the UMAB Medical Center, including pharmacokinetic interpretation of results
- Course Director for graduate level courses in Fundamental Pharmacokinetics, Advanced Pharmacokinetics and Clinical Pharmacokinetics respectively
- Responsible for undergraduate teaching in Applied Pharmacokinetics, and serving as a student advisor

1981 - 1988 Visiting Pharmacokinetic Expert (30% of time), Laboratory of Neurosciences and Pharmacy Development Service, National Institute on Aging and Pharmacy Department, National Institute of Health (NIH), Bethesda, Maryland

- Conduct collaborative research on the pharmacokinetics and pharmacodynamics of drugs in the elderly with special emphasis on patients with Alzheimer's disease
- Provide expert input into the in vitro and clinical research projects being conducted in the Pharmacy Department Research Laboratory
- Provide expert input into the clinical pharmacokinetic consult service for patients at the Clinical Center of NIH
- In-service education for clinical staff in the Department of Pharmacy

1979 - 1981 Director, Drug Concentration Laboratory and
Adjunct Associate Professor of Pharmacology
University of Massachusetts Medical Center
Worcester, Massachusetts

- Director of the a Clinical Pharmacology Consult Service provided by the Department of Pharmacy, including oversight of all bioanalytical methods and pharmacokinetics interpretation of plasma drug levels
- Development of new bioanalytical methods to support federal and

privately funded pharmacokinetic and pharmacodynamic research related to patient care
- Teaching clinical pharmacology to students in the University of Massachusetts Medical School
- Initiation and management of a regional toxicology service to measure drug and chemical exposure in patients admitting to the emergency room, and from consulting physicians
- Mentor for clinical pharmacy students rotating through the Medical Center from the Massachusetts College of Pharmacy

1973 - 1979 Director, Pfeiffer Clinical Pharmacokinetics Research Laboratory
And Associate Professor of Pharmacy, Massachusetts College of Pharmacy, Boston, Massachusetts

- Project Director for industry grants and contracts for in vitro and in vivo studies in biopharmaceutics and pharmacokinetics
- Course Director for all undergraduate and graduate courses in dispensing pharmacy, biopharmaceutics and pharmacokinetics
- Taught laboratory courses in Dispensing Pharmacy
- Major advisor for 5 Ph.D. students and 2 M.S. students.

1971 - 1973 Assistant Professor of Pharmacy, Texas Southern University
School of Pharmacy, Houston, Texas

- Course Director for undergraduate offerings in biopharmaceutics and dispensing pharmacy
- Director of undergraduate research program

EDUCATION

2001 Selected for Advanced Executive Training at the Federal Executive Institute in Charlottesville, Virginia

1971 Doctor of Philosophy (Ph.D.) in Pharmaceutics, Temple University Health Science Center, School of Pharmacy, Philadelphia, Pennsylvania,

1967 Bachelor of Science (B.S.) in Pharmacy Temple University Health Science Center, School of Pharmacy, Philadelphia, Pennsylvania

BOARD ACCREDITATION AND LICENSES

2009 Fellow, Japanese Society for the Study of Xenobiotics

2001 Fellow, American Association of Pharmaceutical Scientists

2000 Fellow, American College of Clinical Pharmacology

1992 Board Certification in Clinical Pharmacology and Diplomate, Applied Pharmacology, by American Board of Clinical Pharmacology

1988 Registered Pharmacist, State of Maryland

1971 Registered Pharmacist, State of Texas

1967 Registered Pharmacist, State of Pennsylvania

PUBLICATIONS

Book Chapters

C.I. Haffajee and L.J. Lesko, Amiodarone in "Drug Treatment of Cardiac Arrhythmias", Futura Press, Mt. Kisco, NY, 1984.

L.J. Lesko, Nonlinear Kinetics of Theophylline Elimination, in "Pharmacokinetic Basis of Drug Treatment", L.Z. Benet, ed., Raven Press, New York, NY, 1984.

L.J. Lesko, High Pressure Liquid Chromatography of Amiodarone in Biological Fluids, in "Methodology in Analytical Chemistry", I. Sunshine, ed., CRC Press, Boca Raton, FL,1985.

L.J. Lesko, Dose-dependent Kinetics of Theophylline, in "Sustained-Release Theophylline", J.H. Jonkman, ed., Excerpta Medica, The Netherlands, 1985.
P.P. Lamy and L.J. Lesko, Altered Drug Action in the Elderly, in "Annual Reports in Medicinal Chemistry", R.C. Allen, ed., American Chemical Society, 1985.

L.J. Lesko, Analytical Methods, in "Drug Studies in the Elderly", N.R. Cutler, ed., Raven Press, New York, NY, 1985.

Y.C. Huang, L.J. Lesko, P. Schwartz, V.P. Shah and R.L. Williams, Topical and Transdermal Generic Drug Products: Regulatory Issues and Resolution, in "Prediction of Percutaneous Penetration", vol. 3B, K.R. Brian, V.J. James and K.A. Walters, ed., 1993.

Shah, V.P., Lesko, L.J. and Williams, R.L., In Vitro Evaluation of Transdermal Drug Delivery, in Transdermal Drug Delivery, M. Gonzalez and G. Flynn, ed., American Chemical Society, 1993.

L.J. Lesko and R.L. Williams, Regulatory Perspective: The Role of Pharmacokinetics and Pharmacodynamics in "Pharmacodynamics: Perspectives in Clinical Pharmacology",

N. Cutler, ed., John Wiley & Sons, New York, NY, 1994.

L.J. Lesko, Bioavailability and Bioequivalence of Modified Release Dosage Forms: General Concepts, in "BioInternational: Bioavailability, Bioequivalence and Pharmacokinetics", K.K. Midha and H.H. Blume, ed., Medpharm. Scientific Publishers, Stuttgart, 1995.

Lesko, L.J., Bioequivalence of Highly Variable Drugs and Drug Products, in Bioavailability, Bioequivalence and Pharmacokinetic Studies, K. K. Midha and T. Nagai, ed., Business Center for Academic Societies Japan, 1996.

Ette, E.I., Miller, R., Gillespie W.R., Huang, S.-M., Lesko, L.J., Williams, R., The Population Approach: FDA Experience. In Balant LP and Aarons L (eds), The Population Approach: Measuring and Managing Variability in Response, Concentration and Dose, Commission of the European Communities, European Cooperation in the field of Scientific and Technical Research, Brussels, 1997.

S-M Huang, P. Honig, L.J. Lesko, R. Temple, and R. Williams, An Integrated Approach to Studying Drug-Drug Interactions. Chapter 18 in "Drug-Drug Interactions: From Basic Pharmacokinetic Concepts to Marketing Issues: Ed. A.D. Rodriguez, Marcel Dekker, 2001

L.J. Lesko and A.J. Atkinson, Jr., Use of Biomarkers and Surrogate Endpoints in Drug Development and Regulatory Decision Making: Criteria, Validation, and Strategies. Annu Rev Pharmacol Toxicol. 2001, 41:347-66..

L.J. Lesko, The Role of FDA in Guiding Drug Development. Chapter in Principles of Clinical Pharmacology, Arthur Atkinson (ed.), 2001.

Rolan P, Atkinson AJ, Lesko LJ. Use of biomarkers from drug discovery through clinical practice: report of the Ninth European Federation of Pharmaceutical Sciences Conference on Optimizing Drug Development. Clin Pharmacol Ther. 2003 Apr;73(4):284-91.

Huang, S-M, Miller M, Toigo, T, Chen, M, Sahajwalla, C, Lesko, LJ, Temple, R. Evaluation of Drugs in Women: Regulatory Perspective– in Section 11, Drug Metabolism/Clinical pharmacology section editor: Schwartz, J), pp 848-859, in "Principles of Gender-Specific Medicine", Ed., Legato M, Academic Press, 2004

Huang, S-M, Lesko, LJ, Application of Pharmacogenomics in Clinical Pharmacology- in Part I: Molecular Medicine, Correlation between genes, diseases and biopharmaceuticals, in "Modern Biopharmaceuticals- Design, Development and Optimization", Ed., Jorg Knablein and RH Muller, Wiley, VCH. 2005

Huang, S-M, Temple, R, Lesko, LJ, Drug-Drug, Drug-Dietary Supplement, and Drug-Citrus Fruit and Other Food Interactions- Labeling Implications, in "Botanical – Drug Interactions, Scientific and Regulatory Challenges", Ed, Lam, F, Huang, S-M, Hall, S, Taylor & Francis, 2006

Goodsaid, F, Huang, S-M, Frueh, F, Temple, R, and Lesko, LJ, Regulatory Guidance and Application of Genomic Biomarkers in Drug Development in "Principles of Clinical Pharmacogenomics", ed., Steven H.Y. Wong, Mark Linder, Roland Valdes, AACC Press, 2006

Lesko LJ and Woodcock J, Regulatory Perspective on Pharmacogenomics, Chapter in Pharmacogenomics, W. Kalow, U. Meyer and R. Tynsdale (eds), Marcel Dekker, 2006

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L.J. Lesko and Sahajwalla C, The Role of FDA in Guiding Drug Development. Chapter in Principles of Clinical Pharmacology, 2nd Edition, Arthur Atkinson (ed.), 2007.

Huang, S-M, Temple, R. Lesko, L., chapter 22, "Adverse Drug Reactions and Drug Interactions" in *Pharmacology and Therapeutics: Principles to Practice.* Ed, Scott Waldman S and Terzic A. 2007

Gobburu JV, Lesko LJ., Quantitative disease, drug, and trial models.
Annu Rev Pharmacol Toxicol. 2009, 49:291-301.

MJ Kim, I Zineh, S-M Huang and LJ Lesko. Role of Pharmacogenetics in Registraion Process 2010. (In Press)

J. Bai, M. Pacanowski and L.J. Lesko, Chapter on Prodrugs in *Prodrugs and Targeted Delivery – Towards Better ADME Properties.* Ed H. Rautio, Wiley, 2010. (In Press)

Sahajwalla, C.G., Lesko, L. J., and Huang, S., The Role of the FDA in Guiding Drug Development. In "Principles of Clinical Pharmacology," 3rd edition Eds Atkinson AJ, Huang SM, Lertora JJ and Markey SP, Elsevier Press. (2012)

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Mould, D. R. and Lesko, L. J., Chapter on *Personalized Medicine – Integrating Individual Exposure and Response Information at the Bedside.* Ed: Springer (2014)

Journal Articles

Lesko, L.J. Biopharmaceutical aspects of geriatric pharmacy. Apothecary 89:22-26,1977.

Kirschenbaum, H.L., Lesko, L.J., Mendes, R.W., Sesin, G.P. Stability of procainamide in 0.9% sodium chloride or dextrose 58 in water. Am. J. Hosp. Pharm. 36(11):1464-1465, 1979.

Lesko, L.J. Dose-dependent elimination kinetics of theophylline. Clin. Pharmacokin. 4(6): 449-459, 1979.

Lesko, L.J., Canada, A.T., Eastwood, G. Pharmacokinetics and relative bioavailability of oral theophylline capsules. J. Pharm. Sci. 68(11): 1392-1394, 1979.

Marion, A., Woodman, T., Lesko, L.J., Canada, A.T. Problems with laboratory method of measuring thiazides in urine. Am. J. Hosp. Pharm. 37(3): 341, 1980.

Lesko, L.J., Brousseau, D., Canada, A.T., Eastwood, G. Temporal variations in trough serum theophylline concentrations at steady state. J. Pharm. Sci. 69(3):358-359, 1980.

Lesko, L.J., Ericson, J., Ostheimer, G. Simultaneous determination of bupivacaine and 2,6-pipecoloxylidide in serum by gas-liquid chromatography. J. Chrom. 182(2):226-231, 1980.

Canada, A.T., Lesko, L.J. Two reasons for unusual therapeutic drug monitoring results in hospitalized patients. Ther. Drug Monit. 2(3):217-219, 1980.

Haffajee, C., Alpert, J., Lesko, L.J. Amiodarone for refractory symptomatic tachyarrhythmia. Circulation 62:576, 1980.

Ganapathi, R., Krishan, A., Wodinsky, I., Zubrod, C.G., Lesko, L.J. Effect of cholesterol content on antitumor activity and toxicity of liposome-encapsulated l-beta-D-arabinofuranosylcytosine in vivo. Cancer Research 40(3):630-633, 1980.

Marion, A., Lesko, L.J., Oliver, C. Procainamide interference with liquid chromatography of theophylline in serum. Ther. Drug Monit. 3(1):107-108, 1981.

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Lesko, L.J., Marion, A., Ericson, J., Siber, G.R. Stability of trimethoprim-sulfamethoxazole injection in two infusion fluids. Am. J. Hosp. Pharm. 38(7):1004-1006, 1981.

Lesko, L.J., Tabor, K.J., Johnson, B.F. Theophylline serum protein binding in obstructive airways disease. Clin. Pharmacol. Ther. 29(6):776-781, 1981.

Woodford, D.W., Lesko, L.J. Relative bioavailability of aspirin gum. J. Pharm. Sci. 70(12) :1341-1343, 1981.

Lesko, L.J., Marion, A., Canada, A.T., Haffajee, C. High pressure liquid chromatography of amiodarone in biological fluids. J. Pharm. Sci. 70(12): 1366-1368, 1981.

Lesko, L.J. Design and evaluation of a drug analysis request/report form for therapeutic drug monitoring (letter). Drug Intel. Clin. Pharm. 16(10) , 782-784, 1982.

Lesko, L.J., Turo, T.T.. Extent of analyst bias in drug-assay results. Amer. J. Hosp. Pharm. 39(3):486-487, 1982.

Ericson, A.J., Milochik, J.A., Lesko, L.J. The fetus: conception to birth, pharmacokinetics in the neonate. On Contin. Pract. 9(2) :13-23, 1982.

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Benotti, J.R., Lesko, L.J., McCue, J.E. Acute pharmacodynamics and pharmacokinetics of oral amrinone. J. Clin. Pharmacol. 22(10) :425-432, 1982.

Palladino, A. Jr., Longenecker, R.G., Lesko, L.J. Lithium test-dose methodology using flame photometry: Problems and alternatives. J. Clin. Psych. 44(1):,6-9, 1983.

Canada, A.T., Lesko, L.J., Haffajee, C.I. Amiodarone for tachyarrhythmia: pharmacology, kinetics, and efficacy. Drug Intel. Clin. Pharm. 17(2):100-104, 1983.

Lesko, L.J., Miller, A.K., Yeager, R.L., Chatterji, D.C. Rapid GC method for quantitation of nifedipine in serum using electron capture detection. J. Chrom. Sci. 21 (9): 41D - 428, 1983.

Haffajee, C.I., Love, J.C., Canada, A.T., Lesko, L.J., Asdourian, G., Alpert, J.S., Clinical pharmacokinetics and efficacy of amiodarone for refractory tachyarrhythmia. Circulation 67(6) :1347-1355, 1983.

Lesko, L.J., Miller, A.K. Physical-chemical compatibility of cromolyn sodium nebulizer

solution - bronchodilator inhalant solution admixtures. Ann. Allergy 53 (3):236-238, 1984.

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McMahon, T., Weiner, M. Lesko, L.J., Emm, T. Effects of age on antidepressant kinetics and memory. Fed. Proc. 44(4):2781, 1985.

Lesko, L.J., Narang, P.K., Yeager, L., Cutler, N.R. Salicylate protein binding in serum from young and elderly subjects as measured by diafiltration. Eur. J. Clin. Pharmacol. 28(3):339-345, 1985

Benotti, J.R., Lesko, L.J., McCue, J.E., Alpert, J.S. Pharmacokinetics and pharmacodynamics of milrinone in chronic congestive heart failure. An. J. Cardiols. 56(10):685-689, 1985.

Cutler, N.R., Haxby, J., Kay, A.D., Narang, P.K., Lesko, L.J., Costa, J.L., Ninos, M., Linnoila, M., Potter, W.Z., Renfrew, J.W. Evaluation of zimelidine in Alzheimer's disease. Cognitive and biochemical measures. Arch. Neur. 42(8):744-748, 1985.

Otto, J., Lesko, L.J. Protein binding of nifedipine. J Pharm. Pharmacol. 38(5):399-400,1986.

Lesko, L.J., Hunter, J.R., Burgess, R.C., Rodgers, G.P. Accumulation of nifedipine after multiple doses. J. Pharm. Pharmacol. 38(6):486-488, 1986.

Lesko, L.J. Dose-dependent kinetics of theophylline. J. Allergy Clin. Immun. 78:723-727, 1986.

Lesko, L.J., Benotti, J.R., Alpert, J.S. Pharmacokinetics of intravenous bepridil in patients with coronary disease. J. Pharm. Sci. 75(10):952-954, 1986.

Lesko, L.J., Fiore, D., Leslie, J. Estimation of protein binding of zimelidine and norzimelidine using cerebrospinal fluid and ultrafiltration. Res. Comm. Psychol. Psych. Behav. 11(2-3):95-111, 1986.

Gutierrez, L.M., Lesko, L.J., Whipps, R. Pharmacokinetics and pharmacodynamics of nifedipine in patients at steady state. J. Clin. Pharmacol. 26(8):587-592, 1986.

McMahon, T.F., Weiner, M., Lesko, L.J., Emm, T. Effects of age on antidepressant

kinetics and memory in Fischer 344 rats. .Pharmacol. Biochem. Behav. 26(2):313-r19, 1987.

Busby, M., Lesko, L.J. Pharmacokinetics interaction between theophylline and chloramphenicol in rats. Drug Metab. Dispos. 15(2):204-206, 1987.

Emm. T., Lesko, L.J., Perkal, M.B. Simultaneous determination of doxepin and nordoxepin in serum using high-performance liquid chromatography. J. Chrom. Biomed. Appl. 419:445-451, 1987.

Weir, M.R., Shen, S.Y., Dagher, FJ. Bentley, F.R., Lesko. L.J. and Sadler, J.H., Evaluation of the effects of cyclosporine and HLA-typed source leukocyte transfusions (apheresis by-products) on the immune systems of highly sensitized prospective renal allograft recipients. Transpl. Proc. 19(1), 731-737, 1987.

Emm, T., Leslie, J., Chai, M., Lesko, L.J., Perkal, M.B. High-performance liquid chromatographic assay of cephalexin in serum and urine. J. Chrom. Biomed. App. 427(1):162-165, 1988.

Emm, T., Lesko, L.J., Leslie, J. Determination of albuterol in human serum by reversed-phase high pressure liquid chromatography with electrochemical detection. J. Chrom. Biomed. App. 427(1):188-194, 1988.

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Rosing, D.R. Relations between serum nifedipine concentration and hemodynamic effects in nonobstructive hypertrophic cardiomyopathy. Am. J. Cardiol. 61(10):830-835, 1988.

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implications for bioequivalence studies. Inter. J. Pharm. 138: 207-213, 1996.

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H. Lennernas, L. Knutson, A. Hussain, L. Lesko, T. Salmonson and G.L. Amidon, Human Effective Permeability of two NSAID's and Two CNS Drugs, ,. Eur. J of Pharm. Sci., 4, S69, 1996.

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Rekhi, G.S., Eddington, N.D., Fossler, M.J., Schwartz, P., Lesko, L.J., and Augsburger, L.L., Evaluation of In Vitro Release Rate and In Vivo Absorption Characteristics of Four Metoprolol Tartrate Immediate-Release Tablet Formulations. Pharm. Develop. Tech. 2(1), 11-24, 1997.

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PATENTS

T.J. Speaker and L.J. Lesko. Microparticulate Material and Method of Making It: Microencapsulation of Drug Substances. 1968

ABSTRACTS (1992-2010)

170 co-authored abstracts, representing posters and podium presentations, have been presented at international and national meetings, primarily the Annual Meetings of the American Society of Clinical Pharmacology and Therapeutics, American College of Clinical Pharmacology, Drug Information Association and the American Association of Pharmaceutics Scientists.

INVITED PRESENTATIONS (1992-2010)

Keynote and/or invited speaker at many national and international meetings of professional organizations including Japanese Society of Clinical Pharmacology and Therapeutics (2010, 2009), Canadian College of Medical Genetics (2010), PKUK Peter Coates Honorary Lecture (2010), Korean Society of Clinical Pharmacology and Therapeutics (2010, 2009 and 2008), JSSX Annual Meeting (2009), World Conference on Clinical Pharmacology (2008), Pharmaceutical Sciences World Conference (2007, 2005), DIA Annual Meetings in US and Europe (2009, 2008, 2007, 2006 and 2005), BIO-IT World Conference (Boston, 2005) and Phacilitate Leaders Forum (Berlin, 2005), American College of Clinical Pharmacology (2008, 2007,2006, 2005, 2004) and American Society of Clinical Pharmacology (2007, 2005, 2004).

Invited speaker for more than 200 podium presentations at international and national conferences, workshops and meetings.

Visiting Scientist at various Universities including Johns Hopkins University Division of Clinical Pharmacology, State University of New York at Buffalo School of Pharmacy, University of Maryland, and the University of Tennessee School Of Pharmacy.

Participated as an ASCPT "Meet the Expert" speaker in 2006.

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Journal of Pharmaceutical Science'
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Pharmacogenomics
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The Pharmacogenomics Journal
The Journal of the American Medical Association

REPRESENTATIVE INDIVIDUAL AWARDS AND HONORS

2014 The **A**merican **A**ssociation of **P**harmaceutical **S**cientist (AAPS) Distinction in Biomarker Research Award

The award is among the highest conferred by AAPS. The award recognizes the continuing, high quality impact that his research on biomarkers has had on drug development, regulatory science and clinical care.

2011 The Gary Neil Prize for Innovation in Drug Development, American Society of Clinical Pharmacology and Therapeutics

This award recognizes outstanding individuals who have been leaders in the field of drug development and stimulated the application of innovative science to clinical drug development

2010 The Coriell Scientific Leadership Award for Personalized Medicine, Coriell Institute for Medical Research

This was the 1st year that Coriell instituted this award – one given to a scientist-clinician for their contribution and another given to a layman for their support of personalized medicine.

2007 University of North Carolina Institute for Pharmacogenomics and Individualized Therapy Award for Clinical Service

This award is presented to honor a person who has made a significant impact on the advancement of individualized therapy across society.

2007 Nathanial B. Kwit Distinguished Service Award for Clinical Pharmacology, American College of Clinical Pharmacology

The primary intent of this award is to recognize accomplishments of a general nature which benefit the field of clinical pharmacology. These may be in the area of teaching, administration, service with ACCP, long-term and wide ranging scientific studies having practical importance, and other service-related functions. It is differentiated for the Distinguished Investigator Award in that it is not intended to recognize any discrete area of scientific investigation, but rather an overall contribution to the field.

2007 Rawls-Palmer Progress in Medicine Award, American Society of Clinical Pharmacology and Therapeutics

The Rawls-Palmer Progress in Medicine Award recognizes a clinical pharmacologist for significant contributions to drug investigation that incorporate the efforts of modern drug research in the care of patients. It was established by Dr. W. B. Rawls to further his commitment to continuing medical education and its impact on patient care.

2000-2010 More than 30 Individual and Group FDA and CDER awards including the prestigious Commissioner's Special Citation in 2006 and 2002 and the 2010 FDA Outstanding Intercenter Scientific Collaboration Award for the development of a Pharmacogenomics Guidance for Industry.

2000 AAPS Meritorious Manuscript Award for the article co-authored with Drs. El-Tahtawy, Tozer, Harrison and Williams, *Evaluation of Bioequivalence of Highly Variable Drugs Using Clinical Trial Simulation II: Comparison of Single and Multiple-Dose Trials Using AUC and Cmax,* Pharmaceutical Research, 15(1), 98-104, 1998.

2000 CDER Leadership Excellence Award for Highest Level of Scientific Expertise and Management Excellence

2000 CDER Excellence in Communication Award

2000 FDA Scientific Achievement Award for Excellence in Regulatory Review Science for Development of the Biopharmaceutics Classification System. This is the FDA's highest level of science award.

2000 CDER Scientific Achievement Award for Excellence in Regulatory Review Science for Development of the Biopharmaceutics Classification System. This is the CDER's highest level of science award.

2000 CDER Excellence in Communication for Clinical Pharmacology Guidance Development

2000 CDER Special Recognition Award for Clinical Research Management

2000 CDER Special Citation Award for QA/QC Initiative and Report

1999 FDA Commendable Service Award

1998 FDA Group Recognition Awards

1999 Certificate of Honor as Outstanding Alumnus, Temple University School of Pharmacy, Philadelphia, Pennsylvania.

1998 Distinguished Lecturer Award in Recognition of Outstanding Achievement in Research and Administration in the Pharmaceutical Industry, Temple University School of Pharmacy Alumni Association

1998 FDA Commissioner's Special Citation Award

1998 CDER Special Recognition Award for Academic Honors Related to Science Achievements

1996 FDA Award of Merit. This is one of FDA's highest level awards for scientific and regulatory science achievements.

REPRESENTATIVE GROUP AWARDS AND HONORS

- CDER Special Recognition Award (2000, 1999, 1998),
- CDER Special Citation Award (2000, 1999),
- CDER Group Recognition Awards (1999, 1998)
- Five CDER Team Excellence Awards for Guidance Development(1998),
- FDA Group Recognition Award for Development of Guidance Related to Fast Track Provision of FDAMA (1999)
- FDA Commendable Service Award for Development of Guidance on Drug Interactions (1999)
- CDER Special Citation Award for Performance in the Development of the Drug-Drug Interaction Guidance (1999)
- CDER Group Recognition Award for Developing BE Gender Guidelines (1998)
- CDER Group Recognition Award for Renal Studies Working Group (1998)
- FDA Commissioner's Special Citation Award for Gelatin Capsule Working Group (1998)
- CDER Team Excellence Award for Development of Clinical Pharmacology Guidances (1998)
- CDER Special Recognition Award for Development of Food Effect BA/BE Guidance (1998)
- CDER Special Recognition Award for Development of In Vitro Dissolution Guidance for IR Dosage Forms (1998)

- FDA Group Recognition Award for Resolution of Issues Related to Women in BE Studies (1998)

1985 Nominee, USP Revision Committee for 1985-1990

1973 Outstanding Man in Science

1972 Outstanding Educator in America

1968 Fellowship, American Foundation for Pharmaceutical Education

1967 Fellowship, National Defense Education Act

CONFERENCE AND WORKSHOP ORGANIZATION

1992-2010 Chaired, Co-Chaired or served on the Organizing Committees of Over 44 FDA Advisory Committee Meeting and FDA External Expert Panels on Various Clinical Pharmacology and Biopharmaceutics Topics. Also, Chaired or Co-Chaired numerous international and national conferences, workshops and meetings co-sponsored by AAPS, ASCPT, ACCP, DIA, FIP and EUFEPS.

1995-2000 Faculty member of Course for industry, academia and regulatory agencies offered by the University of Michigan and University of Uppsala on Drug Absorption

MEMBERSHIP AND OFFICES HELD IN PROFESSIONAL SOCIETIES

- President, American College of Clinical Pharmacology, 2004-2006

  Responsible for development and execution of the new ACCP strategic plan, starting the American Foundation for Clinical Pharmacology (Board Member), initiating a Student Outreach Program, Joint programming with other professional societies (ASCPT, AAPS and AACC), and establishment of the ACCP Past Presidents Club

- American Association of Pharmaceutical Scientists (AAPS)

- American Society of Clinical Pharmacology and Therapeutics (ASCPT)
  - Chair, Clinical and Regulatory Affairs Section (2000- 2002)
  - Co-Chair, Clinical and Regulatory Affairs Section (1997-2000)
  - Board of Directors (1997-1999)

- American College of Clinical Pharmacology (ACCP)
  - Executive Committee (2003-2007)
  - Board of Regents (2001-2004)
  - Regent of the College (2000-2008)

ADJUNCT PROFESSORSHIPS

Provide mentorship to graduate students and give lectures on contemporary topics in pharmacogenomics, biomarkers and general clinical pharmacology principles in drug development and regulatory science

- Ohio State University, School of Pharmacy, 2009 – Present
- University of North Carolina, School of Pharmacy, 2007 - Present
- University of Southern California, School of Pharmacy, 2004 – Present
- University of Florida, College of Pharmacy, 2002 – 2011