

Srikumaran Melethil, Ph.D., J.D.

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Education

JD University of Missouri-Kansas City School of Law, 2002
Admissions: Missouri Bar (# 48508) and W. District of MO - April 2003; USPTO (Reg. No. 57622) - Oct. 2005

PhD Department of Pharmaceutics, State Univ. of NY, Buffalo, NY, 1973

BS & MS Department of Pharmacy, Andhra University, Waltair, India
B. Pharmacy (First Class, First Rank, Gold Medalist), 1967
M. Pharmacy, Manufacturing Pharmacy (First Class), 1968

Employment Experiences

2006- Chair, Department of Pharmaceutical Sciences, University of Findlay, OH

2003- President/CEO, Law and Science Consulting

1979-2002 Schools of Pharmacy and Medicine, University of Missouri-Kansas City
Professor of Pharmaceutics and Medicine, 1988- to 2002; Associate Professor: 1979-1988 (Tenured: 1983)

Honors

Distinguished Scientist, American Association of Indian Pharmaceutical Scientists, 2007
Rho Chi (National Pharmacy Honor Society, UM-KC Chapter) 1990 Teacher of the Year
Elected Fellow, American College of Clinical Pharmacology (1988)
Nageswara Rao Pantulu Gold Medal [First Rank, B. Pharmacy (class of '67)]

Major Professional Experiences/Publications

Teaching PK/PD - Graduate (MS, PhD) and Professional ((BS, PharmD) students
Trained 8 PhDs and 4 MS graduates with emphasis in PK/PD and drug analysis
Publications/Abstracts: about 140 (areas: pharmacokinetics, pharmacodynamics, drug analysis, drug interactions, bioequivalence, clinical pharmacology, gastrointestinal and blood-brain barrier transport of drugs and metals; patent issues in NDAs)
Research Advisor to pre- (MS, PhD) and post-doctoral (PhD, MD and PharmD) students
Scientific Reviewer

- NIH/National Institute of Drug Abuse Grants
- University Missouri Research Board Grants
- Journal Manuscripts
- Editorial Board, Clinical Research and Regulatory Affairs

Pharmacokinetic Consultant

- Pharmaceutical Industry
- Midwest Research Institute, Kansas City, MO
- FDA/Center for Veterinary Medicine (Bioequivalence)

Areas of Expertise

Pharmaceutical Sciences (about 50 peer-reviewed publications)

- Design and Conduct of in-vivo ADME Studies (Pharmacokinetics and Pharmacodynamics)
- Design and Conduct of Drug Transport Studies (in-vitro/ cell culture models)
- Bioavailability/Bioequivalence: Study Design and Data Analysis

- Waiver of In Vivo Bioavailability /Bioequivalence (Biopharmaceutics Classification System)
- Pharmacokinetic Modeling and Software (WinNonlin, SAS, Sigma Plot)
- Methods to Measure Drugs in Biological Fluids (HPLC, AA, GC)
Principal Scientific Officer (1987-1990 for start-up diagnostic company (development of a method to quantify glycosylated albumin)

Patent Law

- NanoPharmaceuticals- Patenting Issues and Regulatory Challenges. Raj Bawa, Srikumaran Melethil, Drew Harris, William Simmons, SciTech Lawyer, Amer. Bar Assn., Fall 2008 (invited)
- Intellectual Property and the Pharmaceutical Sciences, Marilyn Martinez and Srikumaran Melethil, co-editors, Amer. Assn. Pharm. Scientists J. Themed Issue, 2007,
- Patent Issues in New Drug Applications: Perspectives of a Pharmaceutical Scientist-Attorney (AAPS Journal, Vol. 7, # 3, Sep. 2005)
- Short Course Coordinator/Instructor, Patent Law Basics for Pharmaceutical Scientists (Am. Assn. Pharm. Sci., ALA, and Schools of Pharmacy - ongoing)

Food and Drug Law/Regulation

- FDA Proposed Rule for Dietary Supplements (Life Sci. 78, 2049-2053, 2006)
- Instructor, GLP (short course in India, 2005)
- Making the WADA Prohibited List: Show Me the Data. St. Louis Univ. Law J. Vo. 50, No. 1, Fall 2005
- FDA Proposed Rule for Current Good Manufacturing Practice for Dietary Supplements: A Critical Review Life Sciences, 78, 2049-2053, 2006

Expert Witness/Consultations

Drug /Chemical Toxicity

- Affidavit – Effect of hematocrit on breathalyzer test results (Feb. 2009)
- Warfarin and Gleevec toxicity to fetus (deposition, May 2008)
- Marijuana pharmacokinetics (testified before Court of Enquiry, Robbins Air Force base, Georgia, 1994)
- Analytical method used for marijuana detection (testified in MO Court, 2004)
- Prepared reports for law firms on trichloroethylene (1990s) and gentamicin (2005) toxicity
- Lethal injection (affidavit to Supreme Court)

Patents

- Fraser Clemens Martin & Miller (Jake Ward) – Patent prosecution – 2008-to date
- Gerson Lehrman Group phone consultation on patents (Jan. 2008)
- Preparing Clearance Opinions (Hovey Williams, Kansas City, 2005)

Memberships

American Association of Pharmaceutical Scientists
 American Association for the Advancement of Science
 American Intellectual Property Law Association
 Association of University Technology Managers
 Toledo Intellectual Property Law Association
 Hancock County Bar Association

Volunteer Activity

Project Finish, Oak Park Library (GED- High School Equivalency - Math and Science Instructor, 2003-2006)