

## Curriculum Vitae of Srikumaran Melethil, Ph.D., J.D.

### Contact Information

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### Professional Highlights

pharmaceutical scientist, patent attorney, award winning and versatile educator, mentor to graduate and post-graduate students, invited speaker at national and international meetings, expert witness, consultant to industry and government agencies

- Pioneering role in introducing patent law to current and future pharmaceutical scientists
- Served on an advisory committee to the EPA on metal research on in the areas of disposition and toxicity
- Promoted employment in Missouri by obtaining financial support of a startup diagnostic company and providing scientific and technical support
- Research provided understanding of aluminum disposition and mechanisms of toxicity
- Research provided mechanistic insight for reduced brain neurotransmitter levels with aging through the study of blood-brain barrier transport of a precursor amino acid
- International Educator - Enhanced education in India in the areas of pharmaceutical sciences and US patent law

### Current Position(s) and Affiliation

- Adjunct Professor, Dept. of Chemical & Materials Engineering, University of Dayton, Dayton, OH, 2015-to date
- Of Counsel, Shumaker, Loop & Kendrick, LLP, 2017-to date
- President/CEO, Law and Science Consulting, 2003-to date
- Professor Emeritus, Schools of Pharmacy and Medicine, University of Missouri-Kansas City, Kansas City, MO 64110, 2003-to date

### Immediate Past Positions

- Founding Chair, Department of Pharmaceutical Sciences, College of Pharmacy, The University of Findlay, OH 45840, June 2006- August 2010
- Of Counsel, Fraser Clemens Martin & Miller LLC, 2011 -2017

### Areas of Expertise/Skills

- Pharmaceutical Sciences
  - Pharmacokinetics/Pharmacodynamics, (PK/PD), Drug Delivery and Transport//Designing, Conducting and Analyzing Data from PK/PD, Drug

## **Curriculum Vitae of Srikumaran Melethil, Ph.D., J.D.**

Transport and Bioequivalence Studies, Pharmacokinetic Modeling and Simulation; Analytical Method Development

- **Research Publications/Areas/Funding:** Publications: About 50 publications and 140 abstracts. Areas: Pharmacokinetics, Pharmacodynamics, Drug Analysis, Drug Interactions, Bioequivalence, Clinical Pharmacology, Gastrointestinal and Blood-Brain Barrier Transport of Drugs and Metals, Nanopharmaceuticals, Biosimilars. Funding: Federal and State Agencies and Pharmaceutical Industry
  - **Teaching:** Courses in PK/PD to: (1) Graduate (MS, PhD) and Professional (BS, PharmD) Pharmacy students, and (2) Chemical and Biomedical Engineering (BS and MS students)
  - **Academic Advising:** Graduate (PhD. and MS) and Post-Doctoral (PhD, MD and PharmD) students
  - **Scientific Reviewer:** Grants: National Institutes of Health; University of Missouri Research Board; Science Education Partnership, Marion Merrell Dow; Journals: (partial list): Pharmaceutical Research, J. Pharmaceutical Sciences, J. Pharmacology Experimental Therapeutics
  - **Consultant:** FDA/Center for Veterinary Medicine/bioequivalence; pharmaceutical industry/pharmacokinetics; Midwest Research Institute, Kansas City, MO/Pharmacokinetics; Startup Diagnostic Company/Development of a new Diabetes test;
  - **Expert witness/Drug toxicity, Marijuana Pharmacokinetics. Lethal Injection**
  - **Editorial Board Member: Clinical Research and Regulatory Affairs**
- **Drug, Device and Patent Law**
    - **Pharmaceutical Patents/ Litigation Strategist/Support**
    - **Biosimilars/Biologics Price Competition and Innovation Act (BPCIA); litigation strategist/support**
    - **Medical Devices/Class I Registration**
    - **Editorial Board Member: Pharmaceutical Patent Analyst**
    - **Expert Witness/ In court (lethal injection,2012; marijuana pharmacokinetics,1994); Affidavit (drug and chemical toxicity, 1990 - on going)**

### **College Education**

- JD, 2002, School of Law, University of Missouri-Kansas City, Missouri
- PhD, 1973, State University of New York at Buffalo. Thesis Title: Development of a Gas- Liquid Chromatographic Assay for Probenecid and its Metabolites and Examination of the Disposition of Probenecid in Rats and Human Subjects. Advisor: Dr. Walter D. Conway
- M. Pharmacy (First Class, Specialization: Manufacturing Pharmacy), 1968 Department of Pharmacy, Andhra University, Waltair, India
- B. Pharmacy (First Class, First Rank), 1967, Department of Pharmacy, Andhra University, Waltair, India
- Pre-University Course (PUC), Nizam College, Osmania University, Hyderabad, India (1962-1963)

## Curriculum Vitae of Srikumaran Melethil, Ph.D., J.D.

### Professional Licensure

- Member, Missouri Bar, admitted April 2003
- Member, US District Court, Western District of Missouri, admitted April 2003
- Member, United States Patent and Trademark Office, admitted October 2005

### Previous Positions Held

#### Pharmaceutical Sciences

- 1988-02 Professor, Schools of Pharmacy and Medicine, University of Missouri-Kansas City, Kansas City, Missouri 64110
- 1979-88 Associate Professor, Schools of Pharmacy and Medicine, University of Missouri-Kansas City, Kansas City, Missouri 64110.
- 1975-79 Assistant Professor, Department of Pharmaceutics and Pharmacy and Pharmacy Practice, College of Pharmacy, North Dakota State University, Fargo, North Dakota 58102
- 1974-75 Assistant Professor, Department of Pharmacy and Pharmacy Administration, College of Pharmacy and Allied Health Professions, Northeastern University, Boston, Massachusetts 02115
- 1973-74 Assistant Professor, School of Pharmacy, Florida A & M, University, Tallahassee, Florida

### Other Professional Experiences

- 2017-date Team Member, AAPS Year-round Theme Task Force: Biosimilars
- 2015-16 President, Columbus Intellectual Property Association, Columbus, OH
- 2014 Pharmaceutical Patent Law Workshop, Department of Pharmaceutical Sciences, State University of New York at Buffalo, Buffalo, NY, October 24, 2014
- 2013- Chair, IP Subcommittee, Biosimilars Focus Group, American Association of Pharmaceutical Scientists
- 2013 Pharmaceutical Patent Law Fundamental (online), Center for Professional Advancement, East Brunswick, NJ 08816, December 19
- 2012 Expert Witness Testimony, Lethal Injection (US District Court, Alabama)
- 2012 Controlled Release Products-Mesalamine (Literature Review, Consulting)
- 2008 Reviewer, Quantification of Drugs of Abuse and Related Substances in Biological Specimens, National Institute of Drug Abuse, Arlington, VA, August 6
- 2008 Expert Witness Deposition, Warfarin and Gleevec Toxicity to Fetus, May 30
- 2007 Co-editor: Themed Issue: Intellectual Property and the Pharmaceutical Sciences, AAPSJ (publication of the American Association of Pharmaceutical Scientists)

## Curriculum Vitae of Srikumaran Melethil, Ph.D., J.D.

- 2005 Advisory Board, Institute for Strategic Biotechnology, Education and Training (<http://www.isbht.org>)
- 2005-06 Chair, Regulatory Sciences Section, AAPS (American Association of Pharmaceutical Scientists)
- 2004 Proposal reviewer, National Institute on Drug Abuse, project entitled Production, Analysis, and Distribution of Cannabis and Marijuana Cigarettes & Related Compounds, October 5, 2004
- 2004 Proposal Reviewer, Analytical and Stability Testing of Treatment Drugs, National Institute of Drug Abuse/NIH (RFP No. N01DA-48844) Washington, DC, March 21, 2004 (via teleconference)
- 2004 Editorial Board, Indian Journal of Pharmacology
- 2003 Chair-Elect, Regulatory Sciences Section, AAPS (American Association of Pharmaceutical Scientists)
- 2003 Member, Annual Meeting Planning Committee for AAPS 2004
- 2003 Consultant on Project titled “Assessing Dynamic Welfare Effects of Transgenic Plant Technology on Pharmaceutical Production”; PI: Cathryn Carroll, PhD, School of Pharmacy, UMKC
- 2003 Patent Issues in New Drug Applications, American Association of Pharmaceutical Scientists (AAPS) Annual meeting, Salt Lake City, Utah, October 2003 (invited speaker)
- 2003 Proposal Reviewer, Quantitation of Drugs of Abuse by Gas Chromatography/Mass Spectrometry, NIH/National Institute on Drug Abuse, Bethesda, MD, August 7, 2003
- 2003 Expert Witness, Determination of Nandrolone in Human Urine by GC/MS (IOC arbitration panel), June
- 2003 Proposal Reviewer, Synthesis of Drugs of Abuse and Related Compounds, NIH/National Institute on Drug Abuse, Bethesda, MD May 21, 2003
- 1982-02 Pharmacokinetic Consultant, Midwest Research Institute, Kansas City, Missouri.
- 2002- Member, Editorial Board, Clinical Research and Regulatory Affairs
- 2002 Elected Vice Chair, Regulatory Sciences section, AAPS
- 2002 Course Co-ordinator/Instructor, AAPS Annual Meeting short course (1-day) titled “Drug Law Basics for Pharmaceutical Scientists”, Toronto
- 2002 Member, Curriculum Committee, UMKC Pharmacy School
- 2002 Reviewer, SBIR (Phase I and II) proposals (March) NIDA/NIH
- 2002 Expert Witness/Chemical Toxicity
- 2001-2 Consultant, FDA/Center for Veterinary Medicine (Bioequivalence)
- 2001 Elected Secretary/Treasurer, Regulatory Sciences (RS) section, American Association of Pharmaceutical Scientists
- 2001 Reviewer, SBIR (Phase I and II) proposals, NIDA/NIH
- 2001 Fellow, Center for Public Health, UM-KC (Prof. Richards, Dir.)
- 2000-02 Faculty Senator, School of Pharmacy
- 2000 Food and Drug Law Summer Internship (1 week), Food and Drug Law Institute, Washington D.C. (June 2000)

## Curriculum Vitae of Srikumaran Melethil, Ph.D., J.D.

- 2000 Reviewer, Chemical Libraries for Drug Development, National Institute for Drug Abuse February 3, 2000 1:30 to 3:00 pm (Teleconference)
- 2000-01 Member, Government Affairs and Science Policy Committee, American Association of Pharmaceutical Scientists (AAPS)
- 1999-00 Chair, Education Committee, Regulatory Sciences section, AAPS
- 1998-01 Consultant, Inter-Cal Corporation, Prescott, Arizona
- 1998-00 Member, Forensic Center for Law, Medicine and Public Policy, UMKC
- 1998 Reviewer, Special Emphasis Panel N43DA-8-7064 SBIR Project entitled Drug Supply Services Support, National, Institute of Health, Bethesda, MD, January 15, 1998
- 1997 Reviewer, Analytical Services Center for Medications Development Program, (National Institute of Drug Abuse/NIH RFP NO1 DA-7-8074), July 22, 1997, Washington, D.C.
- 1997 Panel of Evaluators, Current Drugs Ltd., London, UK
- 1996 Member, NIH Study Section: Chemistry and Related Sciences Special Emphasis Panel (ZRG3 SSSZ (6), July 11-13, 1996 Washington. D.C.
- 1996 Reviewer, Pharmacokinetic Analysis Resource Center (National Institute of Drug Abuse/NIH Contract NO1 DA-6-8054) July 8, 1996 Washington, D.C.
- 1995 Chairman, Program Committee (RS Section) 1995 Midwest AAPS Regional Meeting Chicago, May 22, 1995
- 1994-96 Member, Campus Promotion and Tenure Committee
- 1994-96 Faculty Senator
- 1994-99 Chair, School of Pharmacy Committee on Admissions and Academic Requirements (Committee Member during 1993-94)
- 1994 Member, UM President's Continuous Improvement Committee
- 1994 Expert Witness, U.S. Air Force (Case involved application of pharmacokinetic principles to urine drug testing of marijuana).
- 1994 Member, NIH Study Section: Technology and Applied Science [ZRG7(SSS-Z)-TAS-02]
- 1990-92 Founder/Secretary, Kansas City Discussion Group/American Association of Pharmaceutical Scientists.
- 1990-92 Faculty Senator
- 1988 Steering Committee Member KCDG Chapter of the American Association of Pharmaceutical Scientists (AAPS)
- 1988 Reviewer, Howard University Faculty Research Grant Support Program.
- 1987-89 Principal Graduate Advisor and Chairman, Graduate Programs Committee, School of Pharmacy, University of Missouri-Kansas City.
- 1986-89 Consultant, Analytical Bio-Chemistry Laboratories, Columbia, Missouri.
- 1986-88 Vice-President, Research, Clinical HPLC, Inc., Kansas City, Missouri
- 1984-85 Consultant, Monsanto Co., St. Louis, Missouri. (increasing milk production in cows through the use of the recombinant Bovine Growth Hormone (rBGH), a genetically engineered hormone)

## Curriculum Vitae of Srikumaran Melethil, Ph.D., J.D.

### Award and Honors- External

- Fellow, American Association of Pharmaceutical Scientists, 2010
- Distinguished Scientist, Amer. Assn. of Indian Pharmaceutical Scientists, 2007
- Elected Fellow, American College of Clinical Pharmacology, 1987
- Lederle Pharmacy Faculty Award, 1974
- Sri Nageshwar Rao Pantulu Medal, Andhra University, 1967 (for obtaining First Class, First Rank, B. Pharmacy degree)

### Award and Honors - Internal

- Professor Emeritus, University of Missouri-Kansas City, 2003
- Senator, University of Missouri-Kansas City Faculty Senate (elected by School of Pharmacy Faculty), 2000-02, 1994-96
- Member, Campus Promotion and Tenure Committee (appointed by Dean, School of Pharmacy) 1994-96
- Rho Chi (Alpha Omega Chapter) Teacher of the Year, University of Missouri-Kansas City, 1990
- Merit Raise, School of Pharmacy, University of Missouri-Kansas City 1989
- Promoted to Full Professor, Schools of Pharmacy and Medicine, University of Missouri- Kansas City, 1988
- Granted tenure, Schools of Pharmacy and Medicine, University of Missouri-Kansas City, 1983

### Current Memberships/Offices

- American Intellectual Property Law Association (AIPLA)
- American Association for the Advancement of Science (AAAS)
- American Association of Pharmaceutical Scientists (AAPS)
- Missouri Bar

### Publications – Pharmaceutical Sciences Research Articles (peer-reviewed)

\*\*= PhD student \* = MS student @= BS student

1. Chemical Stability of Hydrocortisone in Topical Preparation in Proprietary VersaPro™ Cream Base, B.Sarkar, R. Dudley, S. Melethil, J. Speidel, G.M. Bhatt. Innovations in Pharmacy, Vol. 2, No. 3, 1-3, 2011.
2. Proposed Rule for Current Good Manufacturing Practice for Dietary Supplements: A Critical Review Life Sciences, **78**, 2049-2053, 2006
3. Pharmacodynamics of Warfarin in Cats. S.A. Smith, S.L. Kraft, D.C. Lewis, S. Melethil and L.C. Freeman, J. Vet. Pharmacol. Therap., **23**, 339-344, 2000
4. Aluminum Toxicokinetics. C. Exley, E. Burgess, J.P. Day, E.H. Jeffery, S. Melethil and R.A. Yokel, J. Toxicol. Environ. Health, **48**, 569-584, 1996.
5. Standardization in Biological Analyses of Aluminum: What are the needs. M.A. Lovell, W.D. Ehmman, W.R. Markesbery, S. Melethil, C.R. Swyt and P.F. Zatta, J. Toxicol. Environ. Health, **48**, 637-648, 1996
6. Effects of Aging on the Kinetics of Blood-Brain Barrier Uptake of Tryptophan in

## Curriculum Vitae of Srikumaran Melethil, Ph.D., J.D.

- Rats. J-p.Tang and S. Melethil, Pharm. Res. **12**,1085-1091,1995
7. Pharmacokinetics and Pharmacodynamics of Maternal-Fetal Drug Transport of Drugs of Abuse: a Critical Review, S. Melethil, In Membranes and Barriers: Targeted Drug Delivery, National Institute of Drug Abuse Monograph **154**,132-151, 1995
  8. Evaluation of Hepatic Metabolism of Salicylic Acid in Perfused Rat Liver, B.V. Shetty\*\*, M. Badr, and S. Melethil, J. Pharm. Sci., **83**, 607-608, 1994
  9. Increased Blood-Brain Barrier Permeability of Amino Acids in Chronic Hypertension. J-p.Tang\*\*, Z.Q. Xu\*\*, F.L. Douglas, A. Rakhit and S. Melethil, Life Sci., **53**, PL417-420, 1993
  10. Metals Bioavailability and Disposition Kinetics Research Needs Workshop (EPA/HERL1990) Proceedings. J. McKinney (Chair) C. Abernathy, T. Clarkson, J.M. Frazier, O.A. Levander, E. Massaro, A. L. Reeves, R.E. Rodriguez, P. White, B. Beck, M. Costa, E. Jeffery, A. Martell, S. Melethil, R. Reigart, M. Waalkes, and C. Witmer, Toxicol. Environ. Chem., **38**, 1-71, 1993
  11. Kinetics of Aluminum in Rats IV: Blood and Cerebrospinal Fluid Kinetics. Z-C Xu\*\*, J-pTang\*\*, Z-X Xu, S. Melethil. Toxicol. Lett.,**63**, 7-12, 992
  12. Aluminum Induced Acute Cholinergic Neurotoxicity in the Rat, J-H F. Peng, Z-C Xu, Z-X. Xu\*\*, J.C. Parker, Jr., E.R. Friedlander, J-P Tang\*\* and S. Melethil. Molecular Chem. Neuropath., **17**,79-89,1992
  13. Effect of Chronic Hypertension on the Blood-Brain Barrier Transport of Libenzapril in Rats. J-P Tang\*\*, A. Rakhit, F. Douglas, and S. Melethil, Pharm. Res., **9**, 236-243 1992
  14. Kinetics of Aluminum in Rats III: The Effect of Route of Administration. Z-X Xu\*\*, J- P.Tang\*\*, M. Badr and S. Melethil. J. Pharm. Sci., **81**,160-163, 1992
  15. Kinetics of Aluminum in Rats II: Dose-Dependent Urinary and Biliary Excretion. Z-X. Xu, S.M. Pai\*\* and S. Melethil. J. Pharm. Sci., **80**, 946-95, 1991
  16. Pharmacokinetics of Intravenous and Oral Aspirin in Rats. C.J. Fu\*\*, S. Melethil, and W.D. Mason. J. Pharmacokin. Biopharm., **19**, 157-173,1991
  17. Mechanism of Aluminum-Induced Inhibition of Hepatic Glycolysis: Inactivation of Phosphofructokinase. Z. Xu\*\*, L. Fox, S. Melethil, L. Winberg and M. Badr. J. Pharmacol. Expt. Therap. **254**, 301-305,1990
  18. Simultaneous Sampling of Blood, Bile, and Urine in Rats for Pharmacokinetic Studies. Z. Xu\*\* and S. Melethil, J. Pharmacol. Methods **24**, 203-208,1990
  19. Evaluation of the Potential Pharmacokinetic Interaction of Lithium and Alprazolam. R. L. Evans, M. Nelson, S. Melethil, R. Townsend, R.K. Hornstra, and R.B. Smith. J. Clin. Psychopharmacol.**10**, 355-358, 1990
  20. Kinetics of Aluminum in Rats I: Dose Dependent Elimination from Blood after Intravenous Administration, S.M. Pai\*\* and S. Melethil. J. Pharm. Sci., **78**, 200-202, 1989
  21. High Pressure Liquid Chromatographic Assay for Salicylic Acid and Its Metabolites in Rat Urine. B.V. Shetty\*\* and S. Melethil. Anal. Letters **21**, 395-410,1988
  22. Kinetics of Potassium Excretion following Oral Supplements. A. Rakhit, S. Melethil, and W.E. Wagner. Pharm. Res. **4**, 531-535 1988
  23. Comparative Pharmacokinetics of Salicylic Acid and Copper-Salicylate in Rats. B. Shetty\*\* and S. Melethil in Biology of Copper Complexes. J.R.J. Sorensen (ed.).

## Curriculum Vitae of Srikumaran Melethil, Ph.D., J.D.

- Humana Press, NJ, 259-272, 1987
24. Megadoses of Vitamin C: A Pharmacokinetic Evaluation. S. Melethil, M.B. Subrahmanyam, C.J. Chang\*, and W.D. Mason. Ann. N.Y. Acad. Sci. (Third Conference on Vitamin C) **498**, 491-493, 1987
  25. Pharmacokinetics of Gold Sodium Thiomalate in Rabbits. S. Melethil and D. Schoepp\*. Pharm. Res., **4**, 332-336, 1987
  26. Elevation of Serum Aluminum in Humans on a Two-Day Sucralfate Regimen. S. Pai\*\*, S. Melethil, P. Cuddy, and T. Hall. J. Clin. Pharmacol. **27**, 213-215, 1987
  27. The Effect of Dietary Zinc on Selenium Status. K.R. Zinn, J.S. Morris, and S. Melethil. Trans. Amer. Nuc. Soc. **53**, 173-174, 1986
  28. Dose Dependent Absorption and Excretion of Vitamin C in Humans. S. Melethil, W.D. Mason, and J. Chang\*. Int. J. Pharmaceutics **31**, 83-89, 1986
  29. Probenecid Disposition by Parallel Michaelis-Menten and Dose-Dependent Pseudo First Order Processes. J.C. Ho, W.D. Conway, and S. Melethil. J. Pharm. Sci. **75**, 664-668, 1986
  30. Effect of Sucralfate on Phenytoin Bioavailability. T.G. Hall, P.G. Cuddy, C.J. Glass, and S. Melethil. Drug Intell. Clin. Pharm. **20**, 607-610, 1986
  31. Decrease of Serum Zinc Levels after Administration of Semicarbazide. M. Slavik, O. Blanc, S. Pai\*\*, S.K. Melethil, and J. Slavik. Vet. Hum. Toxicol. **28**, 161-162, 1986
  32. The Disposition and Elimination of Stereoisomeric Pairs of Thioridazine-5-Sulfoxide in the Rat. P.W. Hale, S. Melethil, and A. Poklis. Eur. J. Drug Metabol. Pharmacokinet., **10**, 333-344, 1985
  33. Method for Determination of Aspirin and Salicylic Acid in Rat Whole Blood by High Pressure Liquid Chromatography. C.J. Fu\*\*, S. Melethil, and W.D. Mason. Anal. Letters **18** (B3), 269-277, 1985
  34. Pharmacokinetics of Antipyrine, Diazepam, Penicillin and Sulfamethazine in Rats with Fluosol-DA 20% or Stroma-free Hemoglobin. J.M. Kemner, W.G. Snodgrass, S.E. Worley, G.R. Hodges, S. Melethil, C.E. Hignite, and C. Tschantz. Res. Comm. Chem. Pathol. Pharmacol. **46**, 381-400, 1984
  35. Comparison of the Bioavailability of Oral, Rectal, and Intramuscular Promethazine. T.L. Schwinghammer, R.P. Jull, L.W. Dittert, S.K. Melethil, J.F. Kroboth, and V.S. Chungi, Biopharm. Drug Disp. **5**, 185-194, 1984
  36. Liquid Chromatographic Assay for Promethazine in Plasma using Electrochemical Detection. S. Melethil, A. Dutta\*, V. Chungi, and L. Dittert, Anal. Letters **16**(B9), 701-709, 1983
  37. The Effect of Erythromycin on Theophylline Pharmacokinetics in Chronic Bronchitis. G. Reisz, S.K. Pingleton, S. Melethil, and P.B. Ryan, Amer. Rev. Resp. Dis. **127**, 581-584, 1983
  38. Predictability of Plasma Theophylline Concentrations in Hospitalized Patients. S. Melethil, J.D. Carlson, M.T. Haug\*, Drug Intell. Clin. Pharm. **16**, 695-697, 1982
  39. Steady State Urinary Excretion of Theophylline and Its Metabolites in the Presence of Erythromycin. S. Melethil, A. Dutta\*, P.B. Ryan, S.K. Pingleton, and S.J. Kelly, Res. Comm. Chem. Pathol. Pharmacol. **35**, 341-344, 1982
  40. Estimation of the Amount of Drug Absorbed in Acetaminophen Poisoning - A Case Report. S. Melethil, A. Poklis, and H.S. Schwartz, Vet. Human. Toxicol. **23**,



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- 421-423, 1981
41. Binding of Gold to Bovine Serum Albumin Using Flameless Atomic Absorption. S. Melethil, A. Poklis, and V.A. Sagar\*, J. Pharm. Sci., **69**, 585-587, 1980
  42. Blood Levels of Flurazepam and Its Metabolites in Two Hospitalized Patients on Chronic Flurazepam. S.F. Palermo, A. Poklis, and S. Melethil, Res. Comm. Psychol. Psychiat. Behav. **2**, 1-8, 1977
  43. Comparative Pharmacokinetics of Cefamandole, Cephapirin, and Cephalothin in Healthy Subjects and Effects of Repeated Dosing. M. Barza, S. Melethil, S. Berger, and E.C. Ernst, Antimicrob. Agents Chemotherap. **10**, 421-425, 1976
  44. Urinary Excretion of Probenecid and Its Metabolites in Man as a Function of Dose. S. Melethil and W.D. Conway, J. Pharm. Sci. **65**, 861-865, 1976
  45. A Gas Chromatographic Assay for Probenecid and Its Metabolites in Biological Fluids. W.D. Conway and S. Melethil, J. Chromatog. **115**, 222-227, 1975
  46. Excretion of Probenecid and Its Metabolites in Bile and Urine of Rats. W.D. Conway and S. Melethil, J. Pharm. Sci. **63**, 1551-1554, 1974

### Publications – Legal

1. Patentable Subject Matter: The Supreme Court Speaks Again. American Association of Pharmaceutical Scientists (AAPS) Newsmagazine, September 2015, pp. 30-31.
2. Case Law Report: *Eurand, Inc. v. Mylan Pharms Inc.* - Case No. 2011-1399, -1409 (Fed. Cir. Apr. 16, 2012) (reversing district court's finding of obviousness based on bioequivalence data.). (AIPLA Biotech Buzz, June 2012)
3. Federal Pharmacy Law: Jurisprudence Review (Chapter 30); Capstone Pharmacy Review. Eds. B.Mason, Pharm.D., R. Lott, Pharm. D., and D. Parker, Pharm.D., Jones & Bartlett Learning, 2014 (invited)
4. NanoPharmaceuticals - Patenting Issues and Regulatory Challenges. Raj Bawa, Srikumaran Melethil, Drew Harris, William Simmons, SciTech Lawyer, **5** (#2), 10-15, 2008 (Amer. Bar Assn., invited publication)
5. Making the World Anti-Doping Agency Prohibited List: Show Me the Data, St. Louis Law Journal, Vol. 50 (No. 1), 75-89, 2006 (invited)
6. Patent Issues in Drug Development: Perspectives of a Pharmaceutical Scientist Attorney **7**, (#3), E723-727, 2005] (this paper deals with patent infringement issues that arose under the Hatch-Waxman Act, which attempts to balance the interests of brand name and generic pharmaceutical companies; available at <http://www.aapsj.org>)

### Book Chapters

1. Landscape and Consideration of Intellectual Property for Development of Biologics in Biological Drug Products: Development and Strategies, Eds. W. Wang and M. Singh, John Wiley Press, 2013
2. Research Issues in Aluminum Toxicity Ed(s): R.A. Yokel and M.S. Golub, Taylor and Francis, 1997:
  - a. Chap. 6: Aluminum Toxicokinetics, C-Exley, E. Burgess, J.P. Day, E.H. Jeffrey, S. Melethil, and R.A. Yokel, 118-132

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- b. Chap 13: Standardization in Biological Samples of Aluminum: What are the Needs? M.A. Lovell, W.D. Ehmann, W.R. Markesbery, S.Melethil, C.R. Swyt and P.F. Zatta, 241-251.

### Book Reviews

1. Advanced Tutorials for the Bio-medical Sciences: Animations, Simulations, and Calculations Using Mathematica by Charles Pidgeon (**Book Review**). Y. Muthukrishnan and S. Melethil, Amer. J. Pharm Edu. 60, 433-434, 1996
2. Pharmacokinetics - Regulatory, Industrial and Academic Perspectives, 2nd Edn. P.G.Welling and F.L.S. Tse (**Book Review**). Amer. J. Pharm Edu. 59, 435-436, 1995
3. Colonic Absorption and Metabolism by R. Bieck (**Book Review**) Amer. J. Pharm. Edu. 57, 449-450, 1993
4. Pharmaceutical Biotechnology Edited by S.W. Zito (**Book Review**). Amer. J. Pharm. Edu., 56, 490-491, 1992
5. Controlled Drug Bioavailability, Volume 3: Bioavailability Control by Drug: Delivery System Design. Edited by Victor F. Smolen and Lu Ann Ball (**Book Review**), S. Melethil, Amer. J. Pharm. Edu. 49, 340, 1985
6. Biopharmaceutics and Pharmacokinetics - An Introduction by R.E. Notari (**Book Review**), S.Melethil, J. Med. Chem. 19, 736-737, 1976

### Grants and Contracts (\* = PI): Total: \$ 2,515,690 PI: \$ 857,982

1. Stability Testing of Topical Ointments\*. S. Melethil (PI) and A. Basu (co-PI). Medisca Co., Montreal, Canada, \$5000.00 2009
2. Effects of Proprietary Vitamin C and Its Metabolites On Gastrointestinal Absorption of Aspirin\*. Inter-Cal Corporation. \$150,000 (Nov. 2000- March 2003) ; \$ 40,000 (1999-2000) (examined carrier-mediated transport mechanisms involved in vitamin C absorption from the gastrointestinal tract)
3. Blood-Brain Barrier Transport of AG-1343\*, Agouron Pharmaceuticals, (\$20,000) March 1, 1998-February 28, 2000.
4. Analysis of Oxaloplatinum in Dog Blood\*, Debio Pharm Switzerland, \$4725, Apr. 1997 (a contract with the Center of Pharmaceutical Technology, University of Missouri-Kansas City)
5. Blood-Brain Barrier Transport of AG-3340\*, Agouron Pharmaceuticals, (\$20,000) August 1, 1997-July 31, 1999
6. Dental Scientist Ph.D. Training Program UMKC. P. Spencer (PI) My role: co-investigator along with 12 other co-investigators (\$522,010) National Institutes of Dental Research July '96 - June 2000
7. Phase I Single and Multiple-Dose Safety and Pharmacokinetic Clinical Study (NCI Contract No 1-CN-55121-MAO). Contract No 1-CN-55121-MAO). Contractor: A Hurwitz, M.D., Univ. of Kansas; sub-contractor: D. Arneson, Ph.D, Midwest Research Institute, \$838,340, July 1995-June 1997. My role: Pharmacokinetic Consultant
8. Pulmonary Delivery of Peptidomimetic Compounds. S. Melethil (Co-investigator), A. Mitra (PI) and S. Neau (Co-investigator). Marion Merrell Dow, \$175,000 , July 1995 to June 2000
9. Effect of Aging on Brain Uptake and Metabolism of Tryptophan\*. (Univ. MO Research Board Competition), \$32,645. June 1993 - May 1995 (Peer Reviewed)

## **Curriculum Vitae of Srikumaran Melethil, Ph.D., J.D.**

- 10.** Mechanisms of Blood-Brain Transport of Aluminum in Rats\*. NIEHS/NIH, \$106,020. June 1992 - December 1996
- 11.** Effect of Aging on Blood-Brain Barrier Function in Rats\*, Science Education Partnership Research Program, Marion-Merrell Dow Corp., Kansas City, MO. \$50,000. June 1992 - May 1994. (Peer Reviewed)
- 12.** Marion Merrell Dow Science Education Partnership Post-Doctoral Fellowship Award\*, \$65,000. June 1992 - May 1994. (Peer Reviewed) Fellow: Jian-ping Tang, Ph.D.
- 13.** Validation and Application of a Method to Detect Increases in Plasma Aluminum in Humans\*. Kansas City Analytical Services, Shawnee, KS, \$19,000. July 1991
- 14.** Renal Excretion Kinetics of Aluminum in the Rat\*. Research Council, University of Missouri-Kansas City, \$4,000.00. May 1990
- 15.** Developing Models for Studying Pharmacokinetics of Blood-Brain Barrier Transport of Drugs\*. Supported by Ciba-Geigy Corporation, Summit, NJ. Amount: \$68,500. June 1987-91
- 16.** The Protective Effect of Thiosulfate Against Cisplatin-Induced Nephrotoxicity: Clinical and Pharmacokinetic Implications. In collaboration with Uri Alon, M.D., (Principal Investigator), Sarah Morrison Bequest/UMKC: \$12,000. June, 1989. (Peer Reviewed)
- 17.** Development of an Automated HPLC System for Routine Clinical Applications: Specific Applications for the Management of Diabetic Therapy\*. Supported by Clinical HPLC, Inc. (University of Missouri-Kansas City Proposal No. 845003-1). Amount: \$35,165. Year: 1988.
- 18.** Development of an Automated HPLC System for Routine Clinical Applications: Specific Applications for the Management of Diabetic Therapy\*. Supported by Research Assistance Act Grant, State of Missouri, and Clinical HPLC. Amount: \$235,315. Year: 1987. Peer Reviewed.
- 19.** Pharmacokinetics of Ampicillin, Kanamycin, and Phenobarbital in Infants Requiring Extracorporeal Membrane Oxygenation. In collaboration with Dr. Gary Carter, Children's Mercy Hospital. Supported by Katherine B. Richardson Foundation. Amount: \$5,000.00. Year: 1986.
- 20.** Comparative Pharmacokinetics of Drug Copper Complexes: Salicylic Acid – Copper System\*. Weldon Spring Endowment Fund, University of Missouri-Kansas City. \$15,839.60. 1985. Peer Reviewed.
- 21.** Development of an Assay for 6-Mercaptopurine and Its Nucleotide Metabolites\*. Kansas University Medical Center. Amount: \$4,500.00, Year 1984; Amount: \$5,000.00, Year 1986
- 22.** Kinetics of Aluminum in Rats\*. Supported by the University of Missouri-Kansas City Research Council \$3,552.00 1983
- 23.** Evaluation of the Potential Pharmacokinetic Interaction of Lithium and Alprazolam. In collaboration with Drs. Lee Evans and Robijn Hornstra. Supported by the Upjohn Company. Amount: \$20,000.00. Year: 1983
- 24.** Effect of Dietary Level and Zinc on the Organ Distribution and Status of the Essential Nutrient Selenium in the Rat - In collaboration with Dr. Steve Morris, University of Missouri-Columbia. Supported by Weldon Spring Endowment Fund, University of Missouri. Amount: \$30,000.00. Year: 1983.

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25. Bioavailability of Oral Potassium Products\*. Supported by Ciba-Geigy, Ardsley, NY.\$33,946. 1983
26. First Pass Metabolism of Promethazine in Rats\*. Supported by the University of Missouri- Kansas City Research Council \$3,005.00. 1982
27. Evaluation of the Rat as a Model for Study of the Pharmacology and Toxicology of Highly Buffered Aspirin Formulations: Part I - In collaboration with Dr. W. Mason, University of Missouri-Kansas City. Supported by Miles Laboratories. Amount: \$13,396.00. Year: 1982
28. Bioavailability Studies of Promethazine Suppositories\*. Supported by G & W Laboratories, South Plainfield, NJ 07080 \$23,500. 1981
29. Disposition of Promethazine in Hypothermia\*.Supported by the University of Missouri-Kansas City Research Council \$3,364 1980
30. Extrapolation of Animal Data to Humans - In collaboration with H.J. Freedman, R.C Lanman, and D. Yourtee', University of Missouri-Kansas City. Supported by Weldon Spring Endowment Fund. Amount: \$29,994.00. Year: 1980
31. Kinetics of Absorption of Cadmium from the Rat Lung\*. Supported by the University of Missouri-Kansas City Research Council \$3,605.00, 1979
32. Plasma Levels of Adriamycin and Its Therapeutic and Toxic Effects - In collaboration with Dr. O. El-Arini, Chief, Division of Oncology, UND, and Dr. D. Freeman, College of Pharmacy, NDSU. Supported by V.A. Center Office, Washington, D.C. Amount: \$12,000.00. Year 1978
33. Binding of Valproic Acid to Plasma Proteins in Epileptic Patients\*. Supported by the North Dakota State University Committee for Undergraduate Research \$300.00 1978.
34. Trace Element Content of Hyperalimentation Solutions and Additives\* - In collaboration with James Carlson, Clinical Coordinator, V.A. Center, Fargo, ND. Supported by the V.A. Center, Fargo, ND \$3,000 1978
35. Determination of the Binding Characteristics of Flurazepam and Its Metabolites to Plasma Proteins and Examination of Disease States that Modify this Interaction\*. Supported by the V.A. Center, Fargo, ND 58102 \$3,000.00 1976.

### **Presentations/Abstracts: National and International Meetings**

\*\*= PhD student \* = MS student @= BS student

1. What's going on in US Biosimilars Litigation? Centre for Information & Innovation Law (CIIR), University of Copenhagen June 1, 2017
2. Nanopharmaceuticals: Regulatory and Patent Challenges (Invited Keynote Speaker), 2nd Symposium on Nanomedicine and Nanosafety, Colorado Center for Nanomedicine and Nanosafety (CCNN), University of Colorado, Denver, CO, March 24, 2017
3. Pharmaceutical Patent Law S. Melethil and R. Bawa, Center for Professional Development (CfPA), December 13, 2013
4. Nanoparticles and Drug Delivery-Science and Intellectual Property, Center of Excellence for Thin-Film Research and Surface Engineering, Department of Electrical Engineering, University of Dayton, Dayton, Ohio, May 6, 2013
5. How does the body handle nanopharmaceuticals? (invited) NANO 2013-11<sup>th</sup> Annual Conference on Nanotech/Biotech, April 22, 2013, Rensselaer Polytechnic

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- Institute, Troy, NY
6. New Frontiers in Pharmaceutical Sciences Education: Intellectual Property and Drug Law. Indian Pharmaceutical Congress61,, Ahmedabad, India, December 13, 2009 (invited)
  7. Pharmacist Liability: Between a Rock and a Hard Place. EPIC Shareholders' Meeting, Baltimore, MD, September 11, 2009 (invited)
  8. Federal Pharmacy Law 2009 Update, Cardinal Health Retail Business Conference Washington, DC August 1, 2009 (invited)
  9. Pharmacist Liability Then and Now: How has the Legal and Regulatory Landscape Changed, Cardinal Health Retail Business Conference, Washington, DC, August 1, 2009
  10. How the body handles nanopharmaceuticals. NanoBiotech 2008 Rensselaer Polytechnic Institute Troy NY, September 15, 2008 (invited)
  11. Top Ten Patent Cases, the Chartered Institute of Patent Attorneys, London, UK, and Munich Corporate Bar Association, Munich,, Germany (2008) (Member of an American Intellectual Property Lawyers Delegation to London, UK and Munich, Germany)
  12. Critical Updates in Pharmaceutical Patent Law: What Every Biotech Scientist Should Know, National Biotechnology Conference, AAPS, Toronto, June 22-25, 2008, Toronto, Canada (invited) (meeting cancelled)
  13. Nanotechnology: Science and Regulation at the Pipeline to Market Conference sponsored by the Pharmaceutical Education Associates, Arlington, VA, .November 28, 2007 (invited) (meeting cancelled)
  14. Patent Basics; What Pharmaceutical Scientists Need to Know. Drug Delivery 2007: Where Science and Business Meet, Pharmaceutical Education Associates, San Diego, CA, June 8, 2007 (invited)
  15. Intellectual Property and CAM (Complementary and Alternative Medicine). Can. Assn. Pharm. Sci. Montreal, June 1, 2007 (invited)
  16. AAPS Visiting Scientist, University of Cincinnati School of Pharmacy, April 2007 (Workshop on Patent Law Basics for graduate students) (invited)
  17. Short course (1-day ) on Patent Law Basics for Scientists, Association for Laboratory Automation National Meeting, Palm Springs, CA, January 28, 2007 (team taught with Larry Villanueva, Gardner, Groff Santos & Greenwald, PC) (invited)
  18. Short course (1-day ) on Patent Law Basics for Pharmaceutical Scientists, AAPS National Meeting, San Antonio, Texas, November 2006 (I was the course co-ordinator and one of the 3 patent-attorney speakers at this 1-day course) (invited)
  19. Symposium on Biotechnology Law, AAPS National Biotechnology Conference Boston June 2006 (I am the organizer and one of the 4 patent-attorney speakers at this symposium) (invited)
  20. Hatch Waxman Paragraph IV Litigation: Where the Action is: Kansas City Metropolitan Bar Association (2006) (invited)
  21. Drug Discovery and Development: Using Patented Technology without Infringement, AAPS annual meeting HOT TOPIC, Nashville, TN, November 10-14,2005 (talk discussed the recent Supreme Court decision in *Merck v. Integra*) (invited)
  22. Bioequivalence Issues: Global GLP Short Course, Bangalore, India, August 18-20

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- (invited)
23. Making the WADA (World Anti-Doping Agency) Prohibited List: Show Me the Data at the Doping - Ethics, Law & Medicine, Annual Health Law Symposium on Sports Medicine: Doping. Disability and Health Quality, The Center for Health Studies, St. Louis School of Law, St. Louis, MO March 18 (invited)
  24. Intellectual Property (IP) Short Course – Patents, University of Nebraska Medical Center, Omaha, March 13, 2005 (audience was mostly graduate students in pharmaceutical sciences) (AAPS SPOD, invited)
  25. Panel Member, IP Open Forum, University of Nebraska Medical Center, Omaha, March 14, 2005 (invited)
  26. Proposed cGMPs for Dietary Supplements: Rationale and Implications for Product Development, National Institute of Drug Abuse Conference on Naturaceuticals (Natural Products), Nutraceuticals, Herbal Botanicals and Psychoactives: Drug Discovery and Drug- Drug Interactions, Baltimore, MD, November 5-7, 2004 (invited)
  27. Regulation of Plant-Based GM (Genetically Modified) Products: Issues for Drug Development, AAPS Annual Meeting, Baltimore, MD. November 7-11, 2004 (invited)
  28. Patent Strategies for Pharmaceutical Scientists, Univ. of Toronto School of Pharmacy, June 04, 2004
  29. Effects of Ascorbic Acid on Gene Expression. A.K. Chappa, J.T. Tink, M-Cook-Combs and S. Melethil, American association of Pharmaceutical Association Annual meeting, Toronto, November 10-14, 2002.
  30. Ascorbic Acid Transport Across Caco-2 Cell Monolayers, A.K. Chappa\*, M-Cook-Combs and S. Melethil, American Association of Pharmaceutical Association Annual meeting, Toronto, November 10-14, 2002.
  31. Patents. AAPS Graduate Student Outreach Program, AAPS National Meeting, Indianapolis, IN, October 2000 (invited)
  32. Blood-Brain Barrier Transport of AG 1343, Agouron Pharmaceuticals, San Diego, California, May 21, 1998 and 32nd Annual Higuchi Research Seminar, Lake Ozarks, Missouri, March, 1999, (invited).
  33. Aluminum and Blood-Brain Barrier: In-Vitro and In-Vivo Studies, 31<sup>st</sup> Annual Higuchi Research Seminar, Lake Ozarks, Missouri, March, 1998, (invited).
  34. The Blood-Brain Barrier Monocarboxylic Acid Transporter: Structure-Transport Relations. S. Dunnington\*\* and S. Melethil. American Association of Pharmaceutical Scientists 12<sup>th</sup> Annual Meeting, Boston, MA., Nov. 5-9, 1997. Abstract Pharm. Res 14 (115), S-337, 1998.
  35. Kinetics of Blood-Brain Barrier and Blood-CSF Transport of Aluminum in Rats. G.A. Chandorkar\*\* and S. Melethil. American Association of Pharmaceutical Scientists 12<sup>th</sup> Annual Meeting, Boston, MA., Nov. 5-9, 1997. Abstract: Pharm. Res. 14 (115), S-340, 1998.
  36. Preclinical Requirements Including Toxicology, Pharmacology, and Drug Metabolism, Presented at the Short Course on Overview of the U.S. Regulatory Process: Preclinical through Marketing, American Association of Pharmaceutical Scientist 11th Annual Meeting, Seattle, WA, Oct. 27-31, 1996.
  37. Effect of Phosphate and Dichromate on the Analysis of Aluminum using Electrothermal Atomic Absorption Spectrophotometry. B.J. Huber, G.A.

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- Chandorkar\*\* and S. Melethil, Presented at the American Association of Pharmaceutical Scientists 11th Annual Meeting, Seattle, WA, Oct. 27-31, 1996, Abstract: Pharm. Res., 13, (#9, Suppl.) S-66, 1996.
38. Kinetics of Blood-Brain Barrier Transport of Aluminum in Rats. G.A. Chandorkar\*\* and S. Melethil. Presented at the American Association of Pharmaceutical Scientists 11th Annual Meeting, Seattle, WA, Oct. 27-31, 1996, Abstract: Pharm. Res. 13, (#9, Suppl.) S-419, 1996.
  39. Blood-Brain Barrier Permeability of C-sucrose Role of Impurities, V. Muthukrishnan\*\* and S. Melethil. Presented at the American Association of Pharmaceutical Scientist 11th Annual Meeting, Seattle, WA, Oct. 27-31, 1996, Abstract: Pharm. Res. 13, (#9, Suppl.) S-15, 1996.
  40. Pharmacokinetics of Perillyl Alcohol (NSC-641066) In Dogs and Rats. T.L. Morton\*\*, E.I. Evans, D.W. Arneson, L. Malspeis, J.G. Supko, L.R. Phillips, L. Siemann, J. M. Cannon, E. Murrill, J. Tomaszewski, A.C. Smith, S. Melethil and E.J. Little, Presented at the Fourth International ISSX Meeting Seattle, WA; Aug 27-31, 1995; Abstract: ISSX Proceedings Vol. 8.
  41. Aluminum Transport Across the Rat Blood-Brain Barrier: Role of Transferrin. A. Jagarlamudi\* and S. Melethil. American Association of Pharmaceutical Scientists 10<sup>th</sup> Annual Meeting, Miami. November 5-9, 1995. Abstract: Pharm. Res. 12 (#9), S-350, 1995.
  42. Effect of Salt Form on the Transport of Aluminum Across the Blood-Brain Barrier. G.A\*\*. Chandorkar and S. Melethil, American Association of Pharmaceutical Scientists 10<sup>th</sup> Annual Meeting, Miami. November 5-9, 1995. Abstract: Pharm. Res. 12 (#9), S-349, 1995.
  43. Key Participant, Workshop on Issues in Aluminum Research, Vancouver, British Columbia, Canada July 7, 1995 (Sponsored by the University of Kentucky Continuing Education Program) (invited)
  44. Delayed Effect of Intravenous Aluminum on Blood-Brain Barrier Permeability to Sucrose in Rats. V. Yenumala\*\* and S. Melethil American Association of Pharmaceutical Scientists 9th Annual Meeting, San Diego, CA November 6-10, 1994. Abstract: Pharm Res. 11 (#10), S-390 (#PPDM 8230), 1994.
  45. Pharmacokinetics and Transplacental Transfer of Cocaine (CC), Benzoylcegonine (BE) and Norcocaine (NC) in Pregnant Baboons. R. Bhat, G. Chari, J. Muztar, R. Shankar Rao, S. Park, S. Melethil and O. Vidyasagar. Soc. for Pediatric Res., 1994 Meeting; Seattle, Washington, Abstract: Ped. Res. 35 (#4), 82A (abst. #427), 1994 (April).
  46. Pharmacokinetics and Pharmacodynamics of Maternal-Fetal Drug Transport: A Critical Review S. Melethil (invited talk), NIDA Technical Review Meeting on Membrane and Barriers: Targeted Drug Delivery, Bethesda, MD, September 28-29, 1993.
  47. Aluminum Induced Changes in Blood-Brain Barrier Permeability to Sucrose. V. Yenumala\*\* and S. Melethil, American Association of Pharmaceutical Scientists (AAPS) Abstract Pharm. Res. 10 (#10, Supplement), S-414 (Abstract #8461), 1993, 8th Annual meeting, Lake Buena Vista (Orlando), FL, Nov. 14-18, 1993.
  48. Aging Decreases Brain Uptake of Tryptophan. J-p. Tang\*\* and S. Melethil, AAPS 8th Annual meeting, Lake Buena Vista (Orlando), FL, Nov. 14-18, 1993, Abstract Pharm. Res. 10 (#10, Supplement), S-414 (Abstract #8461), 1993 Abstract Pharm.

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- Res. 10 (#10, Supplement), S-414 (Abstract #8462), 1993.
49. Factors Affecting Blood-Brain Barrier Drug Transport. S. Melethil. 26th Annual Higuchi Research Seminar, (Invited) Lake Ozark, MO. March 14-17, 1993.
  50. Effect of Age on Brain Uptake and Metabolism of Tryptophan: Validation of the Brain Perfusion Model. J-p. Tang\*\* and S. Melethil. Science Education Partnership Inaugural Symposium, Kansas City, MO. October 15-18, 1992.
  51. Effect of Acute and Chronic Hypertension on the Brain Uptake of Libenzapril in Rats. J.P. Tang\*\*, S. Melethil, F. Douglas, A. Rakhit and G. Kochak. Society for Neuroscience 11 Annual Meeting, New Orleans, LA, November 12-15, 1991 and 25th Annual Higuchi Research Seminar, (Invited), Lake of the Ozarks, MO. March 8-11, 1992.
  52. Non-linear Elimination Kinetics of Aluminum Chloride in Rats. Z-X. Xu \*\*and S. Melethil. Sixth Annual Meeting of the AAPS, Washington, D.C., November 17-21, 1991.
  53. Osmotic Pressure and Brain Uptake of Libenzapril in Rats. J-P. Tang\*, Z-X\*\*. Xu, S. Melethil, F. Douglas, and A. Rakhit. Sixth Annual Meeting of the AAPS, Washington, D.C., November 17-21, 1991.
  54. Effect of Chronic Hypertension on the Brain Uptake of Amino Acids in Rats. J-P. Tang\*\*, Z-X\*\*. Xu, S. Melethil, F. Douglas and A. Rakhit. Sixth Annual Meeting of the AAPS, Washington, D.C., November 17-21, 1991.
  55. Blood and Cerebrospinal Fluid Kinetics of Aluminum in Rats Z-C. Xu, S. Melethil, J-p.Tang\*\* and Z-X. Xu\*\*. 19th Annual Meeting of the American College of Clinical Pharmacology, Las Vegas, Nevada, November 5-8, 1990. Abstract: J. Clin. Pharmacol. **30**, 836 (#23), 1990.
  56. Effect of Chronic Hypertension on the Blood-Brain Barrier Transport of Libenzapril. J-p.Tang\*\*, A. Rakhit, F. Douglas and S. Melethil. 19th Annual Meeting of the American College of Clinical Pharmacology. Las Vegas, Nevada, November 5-8, 1990. Abstract: J. Clin. Pharmacol. **30**, 837 (#24), 1990.
  57. Effect of Route of Administration on the Disposition Kinetics of Aluminum Sulfate in Rats. Z-X. Xu\*\*, M. Badr, J-p. Tang\*\* and S. Melethil. Fifth Annual Meeting of the AAPS, Las Vegas, Nevada, November 4-9, 1990. Abstract: Pharm. Res. **7**, (#9, Supplement), 5-285 (#PPDM 8316), 1990.
  58. Dose-Dependent Urinary and Biliary Excretion of Aluminum Sulfate in Rats. Z-X. Xu\*\* and S. Melethil. Fifth Annual Meeting of the AAPS, Las Vegas, Nevada, November 4-9, 1990. Abstract: Pharm. Res. **7**, (#9, Supplement), S-285 (#PPDM 8313), 1990.
  59. Effect of Salt-Form on the Disposition Kinetics of Aluminum in Rats. Z-X. Xu\*\* and S. Melethil. Fifth Annual Meeting of the AAPS, Las Vegas, Nevada, November 4-9, 1990. Abstract: Pharm. Res. **7**, (#9, Supplement), S-285 (#PPDM 8317), 1990.
  60. Effect of Aluminum on Rat Brain Cholinergic Enzymes. J. H. Peng, X-C. Xu, Z-X. Xu\*\*, J. C. Parker, E. R. Friedlander, J-p. Tang and S. Melethil. Society of Neuroscience 1990 Annual Meeting, St. Louis, Missouri, October 28 - November 2, 1990. Abstract: Soc.Neurosci. Abstracts. **16**, (Part 1), 446 (#187.10), 1990.
  61. Mechanism of Aluminum-Induced Inhibition of Hepatic Glycolysis. M. Badr, Z-X Xu\*\*, L. Fox S. Melethil and L. Winberg. Society of Toxicology 29th Annual Meeting, Miami Beach, FL, February 12-16, 1990. Abstract: Toxicologist **10** #1,



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- 66 (#262), 1990.
62. Blood-Brain Barrier Transport of Drugs I: Effect of Partition Coefficient. J-p. Tang\*\*, S. Melethil, A. Rakhit and F. Douglas. AAPS 3rd National Meeting, Orlando, FL, October 30 - November 3, 1988. Abstract: Pharm. Res. **5** (#10 Supplement), S-227 (Abstract #PP1513), 1988.
  63. Blood-Brain Barrier Transport of Drugs II: Effect of Hypertension. J-p. Tang\*\*, S. Melethil, A. Rakhit and F. Douglas. AAPS 3rd National Meeting, Orlando, FL, October 30 - November 3, 1988. Abstract: Pharm. Res. **5** (#10 Supplement), S-226 (Abstract #PP1512), 1988.
  64. Decrease of Serum Zinc and Pyridoxal Phosphate Levels during the Diethylstilbestrol Diphosphate Treatment. M. Slavik, S. Pai\*\*, S.K. Melethil, O. Blanc and J. Slavik. 79<sup>th</sup> Annual Meeting of Amer. Assn. for Cancer Res., New Orleans, LA, May 25-28, 1988. Abstract: AACR Proc. **29**, 356 (#1417), 1988.
  65. Pharmacokinetics of Gentamicin in Infants receiving Extracorporeal Membrane Oxygenation (ECMO). G. W. Carter, S. Melethil, M.G. Eisenberg, J.E Dice, B. Short and Roger Boekx, Amer. Pediatric Society and Soc. for Pediatric Research Meeting, Washington, D.C., May 2 - 5, 1988. Abstract: Ped. Res. **23** (#4, Part 2), 256A (#332), 1988.
  66. Pharmacokinetics of Kanamycin in Infants receiving Extracorporeal Membrane Oxygenation (ECMO), G.W. Carter, S. Melethil, V. Meade and F.K. Hall. Amer. Pediatric Society and Soc. for Pediatric Research, Washington, D.C., May 2-5, 1988. Abstract: Ped. Res. **23** (#4, Part 2), 256A(#333), 1988.
  67. Is there a Role for Glycosylated Serum Albumin (GSA) Measurement in the Clinical Management of Diabetes? M.W. Barnard, J. Hollowell, J. Rexroad, S. Melethil and M. Ali. Diabetes **37** (Suppl. 1), 132A (Abstract #520), 1988.
  68. Effect of Copper on Salicylic and Disposition in Rats following I.V. Administration. B. Shetty\*\* and S. Melethil. JUC Pharm. Sci. '87 (APhA), Honolulu, Hawaii, December 2-7, 1987. Abstract: J. Pharm. Sci. **76**, (No. 11), Page: S181 (#I 06-Z-16), 1987.
  69. Biliary and Urinary Excretion of Aluminum in Rats. S. Pai\*\* and S. Melethil. JUC Pharm. Sci. '87 (APhA), Honolulu, Hawaii, December 2-7, 1987. Abstract: J. Pharm. Sci. **76**, (No. 11), Page: S135 (#F 07-Y-19). February 15, 2013
  70. Pharmacokinetic Evaluation of Lithium-Alprazolam Interaction in Human Subjects. S. Melethil, R.L. Evans, M.V. Nelson, R.K. Hornstra, R. Townsend, and R.B. Smith at the International Conference on Clinical Pharmacology and Therapeutics, Bombay, India, November 19-22, 1987. (Invited Paper).
  71. Ultra-Structural Localization of Aluminum in the Aluminum-Perfused Rat Kidney. T. Beringer, S. Pai\*\*, and S. Melethil. 27th Annual Meeting of the Amer. Soc. Cell Biol., St. Louis, Mo., November 16-20, 1987. Abstract: J. Cell. Biol. **105**, (No. 4, Part 2), Page: 225 (#1271), 1987.
  72. The Effect of Dietary Zinc on Selenium Status. K.R. Zinn, J.S. Morris, and S. Melethil. Amer. Nuc. Soc., 1986 Winter Meeting, Washington, D.C., November 16-21, 1986. (Invited Paper).
  73. Megadoses of Vitamin C: A Pharmacokinetic Evaluation. S. Melethil, M.B. Subramanyam, C.J. Chang\*, and W.D. Mason. New York Acad. Sci. Conference on Vitamin C, New York, N.Y., October 8-10, 1986.
  74. Dose Dependent Kinetics of Aluminum after Intravenous Administration in Rats.

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- S. Pai\*, and S. Melethil. Amer. Assn. Pharmaceutical Scientists 1st National Meeting, Washington, D.C., November 2-6, 1986. Abstract: Pharm. Res. **3** (#5), 166S, 1986. (Paper #271).
- 75.** Comparative Pharmacokinetics of Salicylic Acid and Copper-Salicylate in Rats. S.Melethil and B. Shetty\*\*. Second International Conference on Biological Activities of Copper Complexes, University of Arkansas for Medical Sciences, Little Rock, Arkansas, August 11-15, 1986; and Amer. Assn. Pharmaceutical Scientists 1st National Meeting, Washington, D.C., November 2-6, 1986. Abstract: Pharm. Res. **3** (#5), 166S, 1986. (Paper #270).
- 76.** Evaluation of the Potential Pharmacokinetic Interaction of Lithium and Alprazolam. M. Nelson, L. Evans, S. Melethil, R. Hornstra, R. Townsend, and R. Smith. American College of Clinical Pharmacy Annual Meeting, Chicago, Ill., July 1986. Abstract: Drug Intell. Clin. Pharm. **20**, 457-458, 1986.
- 77.** Pharmacokinetics of Aspirin in Rats. C. Fu\*\*, S. Melethil, and W. Mason. Fed. Amer. Exp. Biol. 70th Annual Meeting, St. Louis, Mo., April 13-18, 1986. Abstract: Fed. Proc. **45** (#3), 205, 1986.
- 78.** Changes of Zinc (Zn) Metabolism in Large Bowel Cancer Patients during Treatment with Continuous Intravenous Infusion (CII) of 5-Fluorouracil (5-FU). R. Molina, M. Slavik, C. Fabian, L. Brewster, S. Pai\*\*, and S.K. Melethil. American Association for Cancer Research (AACR) Meeting, Los Angeles, Calif., May 1986. Abstract: Proc. AACR **27**, 173, 1986.
- 79.** Effect of Sucralfate on Phenytoin Bioavailability. T.G. Hall, P.G. Cuddy, C.J. Glass, and S. Melethil. 20th Annual ASHP Midyear Clinical Meeting, New Orleans, La., December, 1985. Abstract: Proceedings Booklet.
- 80.** Decrease of Serum Zinc (Zn) Levels after Administration of Semicarbazide (SCZ). M.Slavik, O. Blanc, S. Pai\*\*, S.K. Melethil, and J. Slavik. Amer. Assn. Clin. Toxicol. (and AAPCC/ABMT/ CAPCC) Annual Scientific Meeting, August 4-9, 1985, Kansas City, Missouri. Abstract: Vet. Hum. Toxicol. **28**, 315, (1985).
- 81.** Decrease of Serum Zinc (Zn) Levels After Administration of Dacarbazine (DTIC). M.Slavik, S.M. Pai\*\*, S.C. Chien, and S.K. Melethil. American Association for Cancer Research, 76th Annual Meeting, Houston, Texas, May 22-25, 1985. Abstract: Proc. Amer. Assn. Can. Res. **26**, 213 (#839), 1985.
- 82.** Computer Aided Instruction in Pharmacokinetics. S. Melethil and S. DeLap. National Symposium on Using Computers in Health Care Education, April 1-2, 1985, University of Nebraska Medical Center, Omaha, Nebraska.
- 83.** Probable Enterohepatic Cycling of 6-mercaptopurine in Children. W.R. Snodgrass, S.D. Smith, R.C. Trueworthy, T. Vats, and S. Melethil. Amer. Soc. Clin. Pharmacol. and Therap., 86th Annual Meeting, March 28-30, 1985, San Antonio, Texas. Abstract: Clin. Pharmacol. Therap. **37**, 230 (1985).
- 84.** Method for Determination of Aspirin and Salicylic Acid in Rat Whole Blood by High Pressure Liquid Chromatography. C.J. Fu\*\*, S. Melethil, and W.D. Mason. APhA Academy of Pharmaceutical Sciences, 37th National Meeting, October 28 - November 1, 1984, Philadelphia, Pennsylvania. Abstract: **14**(2):#17, p.215.
- 85.** Dose Dependent Absorption and Excretion of Vitamin C in Human Subjects. S. Melethil, W.D. Mason, and J. Chang\*. APhA Academy of Pharmaceutical

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- Sciences, 37th National Meeting, October 28 - November 1, 1984, Philadelphia, Pennsylvania. Abstract: **14(2):#75**, p.247.
- 86.** Effect of Hypothermia on the Pharmacokinetics of Promethazine in Hamsters. S. Melethil, A. Dutta\*, and G.E. Resch. APhA Academy of Pharmaceutical Sciences, 37th National Meeting, October 28 - November 1, 1984, Philadelphia, Pennsylvania. Abstract: **14(2):#47**, p.240.
- 87.** Pediatric Clinical Pharmacology of 6-Mercaptopurine: Drug Disposition Variability as a Factor in Leukemia Relapse. W. Snodgrass, S. Smith, P. Klopovich, T. Vats, R. Trueworthy, S. Kisher, S. Melethil, and A. Rachmel. Fed. Amer. Soc. Exp. Biol., 68th Annual Meeting, St. Louis, Missouri, April 1-6, 1984. Abstract: Fed. Proc. **43(#4)**, 951, 1984.
- 88.** Kinetics of Aspirin in Rats Following Intravenous and Oral Administration. C.J. Fu\*\*, S. Melethil, and W.D. Mason. APhA Academy of Pharmaceutical Sciences 35th National Meeting, November 13-17, 1983, Miami Beach, Florida. Abstract: **13(2):#2**, p.194.
- 89.** A Liquid Chromatographic Assay for Promethazine in Plasma. A. Dutta\* and S. Melethil, American Pharmaceutical Association, 130th Annual Meeting, April 9-14, 1983, New Orleans, Louisiana. Abstract: **13(1):#19**, p.86.
- 90.** Effect of Route of Administration on Promethazine Disposition in Rats. J.R. Meng, S. Melethil, American Pharmaceutical Association 130th Annual Meeting, April 9-14, 1983, New Orleans, Louisiana. Abstract: **13(1):#21**, p.94.
- 91.** Erythromycin-Induced Changes in Theophylline Kinetics in Chronic Bronchitis. G.R.Reisz, P.B. Ryan, S. Melethil, and S.K. Pingleton. The 1981 Annual Meeting of the American Thoracic Society, Los Angeles, California, May 15-18. Abstract: Amer. Rev. Resp. Dis., Vol. **125** (No. 4, Part 2), p. 95, (1982).
- 92.** Absorption of Cadmium Chloride Following Intratracheal Instillation in the Rat Lung. S. Melethil and T. Baker@, 31st National Meeting of the APhA Academy of Pharmaceutical Sciences, November 15-19, 1981, Orlando, Florida. Abstract: Vol. **11** (No. 2), p.141 (1981).
- 93.** The Lack of Influence of Erythromycin on Plasma Theophylline. S.J. Kelly, S.K. Pingleton, P.B. Ryan, and S. Melethil - at the 46th Annual Scientific Assembly, Amer.Coll. of Chest Physicians, Boston, Massachusetts, October 26-30, 1980. Abstract: Chest **78(3)**, p.523-524, (1980).
- 94.** Time to Reach Steady State after Administration of a Sustained Release Theophylline Formulation. K. Fendler and S. Melethil, 15th Annual ASHP Midyear Clinical Meeting, San Francisco, California, December 15, 1980. (Paper p.237).
- 95.** The Lack of Effect of Erythromycin on Steady State Plasma Theophylline Levels. S.K.Pingleton, S. Kelly, P. Ryan, and S.K. Melethil - presented at the 1980 Annual Meeting of the Amer. Thoracic Society/Amer. Lung Assn., Washington, D.C., May 18-21, 1980. Abstract: Amer. Rev. Resp. Dis. **121(#4, Part 2)**, 176, (1980).
- 96.** Trace Element Content of Aminosyn Hyperalimentation Solution. J. Carlson, E. Kennedy, and S. Melethil - at the 14th Annual ASHP Midyear Clinical Meeting, December 2-6, 1979, Las Vegas, Nevada (Paper 63-P).
- 97.** Correlation of Steady State Propranolol Plasma Levels with Blood Pressure and Heart Rate in Hypertension. A.J. Dietz, Jr., S. Melethil, and G. Nygard - at the Amer. Soc. of Clin. Pharmacol. and Therapeutics 80th Annual Meeting, March 21-

## Curriculum Vitae of Srikumaran Melethil, Ph.D., J.D.

- 23, Kansas City, Missouri. Abstract: Clin. Pharmacol. Therap. **25**, 221, (1979).
- 98.** Pharmacokinetics of Gold in Rabbits following Intramuscular and Intravenous Administration. S. Melethil and D. Schoepp - at the APhA Academy of Pharmaceutical Sciences 25th National Meeting, November 12-16, 1978. Hollywood, Florida. Abstract: Vol. **8** (No. 2), (1978).
- 99.** Predictability of Theophylline Plasma Concentrations: A Retrospective Study. J.D. Carlson, S. Melethil, and M.T. Haug@ - at the 12th Annual ASHP Midyear Clinical Meeting, December 4-8, 1977, Atlanta, Georgia. Abstract: Page 179.
- 100.** Binding of Gold to Bovine Serum Albumin Using a New Atomic Absorption Spectrophotometric Assay. S. Melethil, V.A. Sagar@, and A. Poklis - at the APhA Academy of Pharmaceutical Sciences 23rd National Meeting, November 14-17, 1977, Phoenix, Arizona. Abstract: Vol. **7** (No. 2), 125 (1977).
- 101.** Urinary Excretion of Probenecid and Its Metabolites in Man at Various Doses. S. Melethil and W.D. Conway - Before the Academy of Pharmaceutical Sciences at the 121st APhA Annual Meeting, August 3-9, 1974, Chicago, Illinois. Abstract: Vol. **4** (No. 1), 121 (1974).
- 102.** GLC Assay of Probenecid and Its Metabolites in Bile and Urine of Rats. W.D. Conway and S. Melethil - at the APhA Academy of Pharmaceutical Sciences 13th National Meeting, November 5-9, 1972, Chicago, Illinois. Abstract: Vol. **2** (No. 2), 209 (1972).

### **Dissertations and Post-Doctoral Projects Total: 22 (MS: 7 ; PhD: 9 Post-Doctoral: 6)**

1. Mechanisms of in-vitro (Caco-2 cell monolayers) Vitamin C Transport. Arvind Chappa, MS degree 2002
2. Mechanisms of Blood-Brain Transport of Aluminum in Rats. Ph.D. Gurudatt Chandorkar, Ph.D. degree, 2002
3. The Mechanism of Aspirin Absorption in the Caco-2 Model of Intestinal Mucosa: Katherine M. Dunnington, R.Ph., Ph.D. degree, 2002.
4. Effect of Aging on Blood-Brain Barrier Function in Rats. Eshwari Yenumala, PhD degree, 2002.
5. Transport of Salicylic Acid Across Caco-2 Cell Monolayers: Effects of Concentration, pH, Aspirin, Ibuprofen and Ascorbic Acid. Lei Hong, MS degree, 2002.
6. Factors Affecting In-vitro and In-vivo Blood-Brain Barrier Permeability. Terri Morton, Ph.D, degree, 2001.
7. Aluminum Transport Across the Rat Blood-Brain Barrier: Role of Transferrin. Aparna Jagarlamudi, MS degree, 1995
8. Effect of Aging on Brain Uptake and Metabolism of Tryptophan Jian-ping Tang, PhD (Post-doctoral Fellow, 1991-1993).
9. Blood-Brain Barrier Uptake of Alcohol in Rats. Mike Spradlin, MD (Anesthesiology Resident 1994 (summer)
10. Fentanyl Pharmacokinetics and Pharmacodynamics in Patients on Extra Corporeal Membrane Oxygenation [ECMO]. Tung N. Giep, M.D. (Neonatal Fellow) 1993-94.

## Curriculum Vitae of Srikumaran Melethil, Ph.D., J.D.

11. Effect of Hypertension on the Blood-Brain Barrier Transport of Libenzapril. Jianping Tang, PhD degree, 1991.
12. Mechanisms of Dose-Dependent Kinetics of Aluminum in the Rat. Rick Xu, PhD degree, 1991.
13. Pharmacokinetics of Lithium-Alprazolam Interaction (Post Doctoral Fellow:Merlin Nelson, Pharm.D.Fellow, 1989).
14. Comparative Pharmacokinetics of Copper-Drug Complexes: I. Salicylic Acid – Copper System Bhasker Shetty, PhD degree, 1988.
15. Kinetics of Aluminum in Rats. Sudhakar Pai, PhD degree, 1989.
16. Pharmacokinetics of Gentamicin and Kanamycin in Infants receiving ECMO. Gary Carter, D.O. (Neonatal Fellow), 1989.
17. Effect of Hypothermia on the Pharmacokinetics of Promethazine in Hamsters. Atanu Dutta, MS degree, 1987.
18. Pharmacokinetics of Aspirin in Rats. Joky Fu, PhD degree, 1986 (co-advisor with Dr. William Mason).
19. Kinetics of Vitamin C in Human Subject at Various Doses. Jo Chang, MS degree, 1983 (co-advisor with Dr. William Mason).
20. Pharmacokinetics of Erythromycin-Theophylline Interaction, 1983. George Reisz, M.D. (Pulmonary Fellow), 1983.
21. Predictability of Theophylline Plasma Concentration in Hospitalized Patients. Marc Haug III, MS degree, 1978.
22. Binding of Gold to Bovine Serum Albumin (for M.S. degree) - completed 1977. Vidya Sagar, MS degree, 1977.

### Presentations and Abstracts - Regional/Local Meetings

1. Drug Dosing in the Elderly: Pharmacokinetic and Pharmacodynamic Considerations. VA Medical Center, Leavenworth, KS April 3, 1996 (invited)
2. Pharmacokinetics of 4-Ipomeanol in Plasma and Urine. T Morton, G.A. Turner, A. Biava, E.A. Murrill and S. Melethil 29th Regional ACS Meeting, Kansas City, MO November 2, 1994
3. Generic Substitution: Theory and Practice. (Invited Presentation) S. Melethil, Sponsored by the Greater Kansas City Society of Hospital Pharmacists, Kansas City, MO, October 14, 1988.
4. Blood-Brain Barrier Transport of Drugs - Brain Uptake Index Studies. J.P. Tang, S. Melethil, and A. Rakhit. Research Day Poster, Medical School, University of Missouri- Kansas City, March 24-25, 1988.
5. Effect of Copper on Salicylic Acid Disposition in Rats Following IV Administration. B.V. Shetty and S. Melethil - at the 19th Annual Pharmaceutics Graduate Student Research Meeting (Podium Presentation), Ann Arbor, MI, June, 1987.
6. Dose-Dependent Kinetics of Aluminum after Intravenous Administration in Rats. S. Pai and S. Melethil - at the 18th Annual Pharmaceutics Graduate Student Research Meeting (Contributed Poster Presentation), Chicago, IL, June, 1986.
7. Comparative Pharmacokinetics of Salicylic Acid and Its Copper Complex. B. Shetty and S. Melethil - at the 18th Annual Pharmaceutics Graduate Student Research Meeting (Contributed Poster Presentation), Chicago, IL, June, 1986.

## Curriculum Vitae of Srikumaran Melethil, Ph.D., J.D.

8. Clinical Pharmacology of 6-MP. S. Melethil, R. Trueworthy, and S. Murti, 8th Annual Pediatric Hematology/Oncology Symposium (Sponsored by the Univ. of Kansas Medical Center) Kansas City, Missouri, April 7, 1986. (Invited Paper).
9. Use of L'vov Platform to Increase Sensitivity of Atomic Absorption Assay for Aluminum. S.M. Pai and S. Melethil - at the 19th Annual Conference on Trace Substances in Environmental Health, Columbia, Missouri, June 3-6, 1985 and the 17th Annual Pharmaceutics Graduate Student Research Meeting, Univ. of Kentucky, Lexington, Kentucky, June 19-21, 1985.
10. Effects of Selenium on the Distribution of Intratracheally Administered Cadmium in Rats. N. Weaver and S. Melethil - at the Vistas in Pharmacy Symposium, Alpha Omega Chapter of Rho Chi, Kansas City, Missouri, March 4-5, 1983. Won Second Prize in Undergraduate Research Competition.
11. Absorption of Cadmium Chloride following Intratracheal Instillation in the Rat Lung. S. Melethil, S. Reynertson, T. Baker, and H. Freedman - at the 16th Annual Conference on Trace Substances in Environmental Health, Columbia, Missouri, May 31-June 3, 1982.
12. Kinetics of Absorption of Cadmium Chloride from Rat Lung. S. Melethil, W. Cowden, S. Reynertson, and T. Baker - at the 1982 Annual Meeting of the Missouri Academy of Science, Point Lookout, Missouri, April 23-24, 1982.
13. Alteration of Theophylline Kinetics by Erythromycin in Chronic Bronchitis. G.R. Reisz, S.K. Pingleton, P.B. Ryan, and S.K. Melethil, American Federation for Clinical Research (Midwest Section), Chicago, Illinois, November 5, 1981.
14. Pharmacokinetics of Gold in Rabbits. D. Schoepp and S. Melethil - at the 70th Annual Meeting of the North Dakota Academy of Science, Grand Forks, North Dakota, April 28- 29, 1978. Abstract: Academy Proceedings 32 (Part I), 33, (1978).
15. Binding of Gold to Bovine Serum Albumin. V.A. Sagar, S. Melethil, and A. Poklis - at the 69th Annual Meeting of the North Dakota Academy of Science, Minot, North Dakota, April 29-30, 1977. Abstract: Academy Proceedings 31 (Part I), 28, (1977).

### Continuing Education - Publications and Presentations

1. Co-ordinator and Instructor, Drug Law Basics for Pharmaceutical Scientists, AAPS Short course, Toronto, October 2002
2. Generic Substitution: Theory and Practice, sponsored by the University of Missouri-Kansas City School of Pharmacy, March 21, 1989.
3. A Symposium on Drug Product Selection, sponsored by University of Missouri-Kansas City School of Pharmacy and Lederle Laboratories, March 17, 1985. Presented lectures titled: (a) Bioavailability and Therapeutic Equivalence (b) Biopharmaceutics and Blood Levels
4. Drug Product Selection, S. Melethil and R.N. Connors, Missouri Pharm. 58, 12-13,23 (1984).
5. Pharmacology for Health Professionals - Individualization of Drug Therapy, S. Melethil, Kansas City, Missouri, May 18-19, 1982.
6. Pharmacology for Nurses by Home Study (Vol. 1, #3) - Rational Drug Therapy and Drug Missouri 64113, 1980.

## **Curriculum Vitae of Srikumaran Melethil, Ph.D., J.D.**

7. Participated in Seminar for Pharmacists, sponsored by the American Cancer Society, Missouri Division, Columbia, Missouri, Nov. 11, 1979.

### **International Educational Activities**

- Sarasvathi Vidya Bhavan College of Pharmacy, Mumbai, India, Advisor, 2000-2005
  - Lead role in establishing a formal memorandum of understanding (MOU) between this new Indian College of Pharmacy and the School of Pharmacy, University of Missouri- Kansas City for faculty and student exchange
  - This MOU was very helpful to the Indian College in accreditation matters
  - Provided programs in pharmacokinetics and US patent law
- College of Pharmacy, RAK Medical & Health Sciences University, Ras Al Khaimah, United Arab Emirates
  - This is a new College and is seeking US collaboration in establishing their pharmacy program
  - I have a talk titled "Pharmacy education and research in the US" in December 2009
  - MOU for faculty and student exchange (correspondence in progress)

### **Editorial Services for Learned Journals in Pharmaceutical or Related Journals**

#### **• Grant Reviewer**

- Reviewer, Quantification of Drugs of Abuse and Related Substances in Biological Specimens, National Institute of Drug Abuse, Arlington, VA, August 6, 2008
- Proposal reviewer, National Institute on Drug Abuse, project entitled Production, Analysis, and Distribution of Cannabis and Marijuana Cigarettes & Related Compounds, October 5, 2004
- Proposal Reviewer, Analytical and Stability Testing of Treatment Drugs, National Institute of Drug Abuse/NIH (RFP No. N01DA-48844) Washington, DC March 21, 2004 (via teleconference)
- Proposal Reviewer, Quantitation of Drugs of Abuse by Gas Chromatography/Mass Spectrometry, NIH/National Institute on Drug Abuse, Bethesda, MD, August 7, 2003
- Proposal Reviewer, Synthesis of Drugs of Abuse and Related Compounds, NIH/National Institute on Drug Abuse, Bethesda, MD May 21, 2003
- Reviewer, SBIR (Phase I and II) proposals (March) NIDA/NIH, 2002
  - Chemical Libraries for Drug Development, National Institute for Drug Abuse
- February 3, 2000 1:30 to 3:00 pm (Teleconference)
- Member, NIH Study Section: Technology and Applied Science [ZRG7(SSS-Z)-TAS-02] 2002, 1994
- Member, Technical Review "Membranes and Barriers: Targeted Drug Delivery", National Institute of Drug Abuse/NIH, Rockville, MD. Sept. 28-29, 1993
- Dutch Cancer Society Research Proposal (2002)
- Reviewer, Howard University Faculty Research Grant Support Program.(1998)

#### **• Journal Reviewer (1980 -2002)**

## Curriculum Vitae of Srikumaran Melethil, Ph.D., J.D.

- Clinical Research and Regulatory Affairs
  - International. J. Pharmaceutics
  - Pharmaceutical Research
  - J. Pharmaceutical Sciences
  - J. Experimental Pharmacology and Therapeutics
- **Editorial Boards**
    - Advisory Board, *Update*, Food and Drug Law Institute (2011-2014)
    - Clinical Research and Regulatory Affairs (2006-
    - Indian Journal of Pharmacology (2004-2006)
  - **AAPSJ Theme Editor**
    - Intellectual Property Law and the Pharmaceutical Sciences (2007)  
Guest Editor: Marilyn N. Martinez and Srikumaran K. Melethil (my key responsibility was to check of legal accuracy and provide suggestions to authors to improve reader interest in these not so familiar subject matter). I was delighted to see that various AAPS sections supported my idea to make Intellectual Property the theme for the 2006 National Meeting.

### Organization of Programs

- **Short Courses**
  - Patent Basics for Scientists, Association of Laboratory Automation Annual Meeting, Palm Springs, CA, 2007. I conceived the idea and was the organizer and moderator. I taught this with another patent attorney.
  - Patent Basics for Pharmaceutical Scientists, coordinator/instructor AAPS Annual Meeting, San Antonio, TX 2006. I conceived the idea and was the organizer, moderator of the event. I taught this course with 3 other patent attorneys.
  - Global GLPs, Bangalore India (2005); I was an instructor and organizer. It was sponsored by the Institute for Strategic Biotechnology, Health and Training (<http://www.isbht.org>). The Institute promotes pharmaceutical sciences and drug regulation education in India.
  - Drug Law Basics (FDCA) for Pharmaceutical Scientists. Course, AAPS Annual Meeting, Toronto 2002. I conceived the idea and was the organizer and moderator of the event. I taught this course with 3 other attorneys.
- **Symposia**
  - Symposium on Biotechnology Law, AAPS National Biotechnology Conference Boston June 2006 (I am the organizer and one of the 4 patent-attorney speakers at this symposium) (invited)
- **Workshops (India)**
  - Nizam Institute of Medical Sciences (1996); this program was inaugurated by Dr. Reddy; Dr. Reddy's laboratory is now a leading pharmaceutical company in India
  - Jawaharlal Institute of Postgraduate Medical Education and Research (2000); this is one of the leading biomedical research institutions in India



## **Curriculum Vitae of Srikumaran Melethil, Ph.D., J.D.**

- SVB College of Pharmacy, Mumbai (2000)
- Good Laboratory Practices, Bangalore, India, July 2005, Institute for Strategic Biotechnology, Health and Training (ISBHT)
- Biosimilars Conference, India 2011 (in planning stage)

### **Service to Scientific Organizations: American Association for Pharmaceutical Scientists (AAPS)**

- **Regulatory Sciences S Section Leadership**
  - Chair, 2005 (promoted science based regulation and Cost-benefit analysis of regulation)
  - Chair-Elect 2004
  - Vice-Chair 2003
  - Secretary/Treasurer 2001
  - Chair, Education Committee, 1999
- **Graduate Student Education (Patent Law)**
  - University of Denver, Colorado, 2010 . sponsored AAPS Graduate Student Chapter
  - University of Cincinnati School of Pharmacy, AAPS Visiting Scientist, 2007
  - University of Utah, Salt Lake 2006 sponsored by Student/Postdoc Outreach and Development, AAPS
  - University of Nebraska, Omaha 2005 sponsored AAPS Graduate Student Chapter
  - University of Toronto School of Pharmacy (2004) (during an AAPS program organization meeting)
  - University of Missouri-Kansas City (2001) sponsored AAPS Graduate Student Chapter
  - Graduate Student Outreach Program, AAPS National Meeting, Indianapolis, 2000
- **Discussion Group**
  - Founder/Secretary, Kansas City Discussion Group (KEDGE), 1990-92
  - Steering Committee Member, to establish the KEDGE Chapter, 1988-89
- **Focus Group**
  - Chair, IP Subcommittee, Biosimilars Focus Group (2013-)
  - Founder and Chair Intellectual Property Focus Group (2005)
- **Contributions to Newsmagazine**
  - The FDA Exemption: Using Patented Information without Infringement in Drug Discovery and Development, Feb. 2006, p. 20
  - Recent Patent Decisions and Implications for Drug Development April 2005
- **Webinar**
  - Patent Issues in Drug Development: Perspectives of a Pharmaceutical Scientist-Patent Attorney, April 2010 (AAPS)
- **Other service**

## Curriculum Vitae of Srikumaran Melethil, Ph.D., J.D.

- Member, Annual Meeting Planning Committee, 2004
  - Drug Regulation vs. Antimicrobial Resistance, AAPS Symposia (co-organizer: Marilyn Martinez, Ph.D.)
  - Member, Government Affairs and Science Policy Committee, 2000
  - Chairman, Midwest Regional Program Committee (RS Section), 1995
  - Chairman, Education Committee, Regulatory Affairs Section, 1993-94
- **Volunteer Work:** Math and Science Teacher, K-12 (most recent)
    - Advisor, Springfield Promise Neighborhood Summer Enrichment Program, 2015
    - Member, Springfield High School Guidance Group, 2013-2014
    - Volunteer, OGT Boot camp 2013
- **Courses Taught**

Subject and Institution	Level/Major	Year(s)
Drug Delivery-Science and Patents University of Dayton (UD)	MS (Biomed. Engr.)	2015
Advanced Pharmacokinetics UD	B.S. (Chem. Engr.)	2017
Pharmacokinetics University of Missouri-Kansas City (UMKC) and The University of Findlay (UF)	BS/PharmD (Pharmacy majors)	1973-2002 (UMKC), 2006-2010 (UF)
	Ph.D./MS (Pharmacy majors)	1980-2002 (UMKC)
Physical Pharmacy UMKC and UF	BS	1975-1979 (UMKC); 2006-2008 (UF)
Pharmacy Law UF	PharmD	2009-2010 (UF)
Health Care Regulation and Public Policy UF	MBA	2007

- **Community Activities**
  - Improving K-12 Education/Volunteer math and science tutor
  - Adult Education/British India - Corporate Power and Colonization

October 20, 2017