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EDUCATION

B.S., Pharmacy (1968), National Taiwan University, Taipei, Taiwan M.S., Physical Chemistry (1973), Auburn University, Auburn, Alabama Ph.D., Pharmaceutical Chemistry/Pharmacokinetics (1977), University of California, San Francisco, California

PROFESSIONAL EXPERIENCE

- 1969-70 Detail Pharmacist

 Japan Shionogi Pharmaceutical Company, Taipei, Taiwan
- 1977-80 Assistant Professor, College of Pharmacy University of Florida, Gainesville, Florida
- 1980-86 Associate Professor, College of Pharmacy University of Houston, Houston, Texas
- 1987-89 Manager of Clinical Research KV Pharmaceutical Company, St. Louis, Missouri
- 1989-91 Assistant Director, Clinical Pharmacology Wyeth Research, Philadelphia, Pennsylvania
- 1991-92 Associate Director, Clinical Pharmacology Astellas Healthcare, Deerfield, Illinois
- 1992-93 Director, Pre-clinical Development and Analytical Chemistry Greenwich Pharmaceuticals, Philadelphia, Pennsylvania
- 1993-98 Vice President, Clinical Research and Business Affairs Orlando Clinical Research Center, Orlando, Florida
- 1998-02 President, Promed Clinical Research Center (formerly CRC/FL)
 Orlando, Florida
- 1999-01 Scientific Advisor, Bureau of Pharmaceutical Affairs, Department of Health, Taiwan
- 2002-05 Principal, Advanced Pharma Consulting, Orlando, Florida
- 2005- Professor, Pharmaceutical Sciences, School of Pharmacy, Palm Beach Atlantic University, West Palm Beach, FL
- 2006- Scientific Advisory Board, PhytoMedicals, Inc, Princeton, NJ

PROFESSIONAL SOCIETY MEMBERSHIP

- 1971-73 Lamda Phi Upsilon Chemical Society
- 1973-86 American Pharmaceutical Association
- 1977- American Association of Colleges of Pharmacy
- 1980- American Society for Clinical Pharmacology and Therapeutics
- 1983- American College for Clinical Pharmacology

- 1986- American Association of Pharmaceutical Scientists
- 1997- Association of Clinical Research Professionals
- 1997- Drug Information Association

COLLEGE/UNIVERSITY SERVICES

- 1977-80 Graduate Admissions Committee, College of Pharmacy, University of Florida
- 1979-80 Graduate Seminars Committee, College of Pharmacy, University of Florida
- 1979-80 Curriculum Committee, College of Pharmacy, University of Florida
- 1980-86 Graduate Studies Committee, College of Pharmacy, University of Houston
- 1980-86 Student Advising Committee, College of Pharmacy, University of Houston
- 1982-83 Intramural Research Grant Committee, University of Houston.
- 1982-84 Post-graduate Study Committee, College of Pharmacy, University of Houston
- 1985-86 Limited Grant in Aid Committee, University of Houston.
- 1986-87 Tenure and Promotion Committee, College of Pharmacy, University of Houston
- 2006-11 Admissions Committee, School of Pharmacy, Palm Beach Atlantic University
- 2007-08 Academic Technology Committee, Palm Beach Atlantic University
- 2007-08 Grant Reviewer, Quality Initiative Faculty Research, Palm Beach Atlantic University
- 2008-11 Research Resources Committee, School of Pharmacy, Palm Beach Atlantic University
- 2008-11 Faculty Advocacy Committee, School of Pharmacy, Palm Beach Atlantic University
- 2009-10 Faculty Promotion Advocacy Committee, Palm Beach Atlantic University

PROFESSIONAL SOCIETY SERVICES

- 1978 Chairman, Basic Pharmaceutics Section, 125th Annual Meeting of the American Pharmaceutical Association.
- 1979 Instructor, Continuing Education Program, Florida Pharmacists Association.
- 1982 Paper Screening Committee, Texas Society for Hospital Pharmacists.
- 1985 Symposium Coordinator, 133rd Annual Meeting of the American Pharmaceutical Association.
- 1996 Communications Committee, American Society for Clinical Pharmacology and Therapeutics.
- 1998 Vice Chair, Public Affairs and Communication Committee, American Society for Clinical Pharmacology and Therapeutics.

U.S. GOVERNMENT SERVICES

- 1979-80 National Medical Advisory Committee (Drug Labeling), FDA
- 1982-83 Special Study Section (Physiological Biochemistry), NIH
- 1983-84 Special Study Section (End-Stage Renal Disease Program), NIH
- 1983- Concept Summary Review Committee, National Institute on Drug Abuse.
- 1984-85 Project Officer, Research Technology Branch, National Institute on Drug Abuse
- 1985-86 Consultant, Pharmacokinetic Program, National Institute on Drug Abuse
- 1986-87 Special Review Committee, Small Business Innovation Research Grant, ADAMHA

1989-90 Contract Review, Extramural Program, National Institute on Drug Abuse 1992-00 Research Grant Review, Alcohol, Drug Abuse, and Mental Health Administration 2000- Research Grant/Contract Review, National Institute on Drug Abuse, NIH

BOOK/JOURNAL REVIEW

<u>Pharmacokinetics.</u> Gladtke and Heimann, eds. Gustav Fischer Verlag, Stuttgart, New York, 1980

<u>Biopharmaceutics and Clinical Pharmacokinetics: An Introduction</u>, R.E. Notari, Marcel Dekker, Inc., New York, N.Y., 1987

J. Pharmacokinet. Biopharm, 1980, 1982, 1984

The Association of Official Analytical Chemist, 1980-1981

Biopharmaceutics and Drug Disposition, 1981-1987

J. Clin. Pharmacol. 1983-85

J. Pharm. Sci. 1984

Clin. Pharmacokinet., 1984

Am. J. Kidney Diseases, 1985

Pharmaceutical Research, 1990-1991

J. Medical Systems 2009-

PUBLICATIONS

Book chapter

- 1. Lee, C.S. and Benet, L.Z.: Ethambutol hydrochloride. In: <u>Analytical Profiles of Drug Substances</u>. K. Florey, Ed., Vol.7, 1978, Academic Press, Inc., pp. 231-249.
- Lee, C.S. and Chiang, C.N.: Maternal-fetal Transfer of Abused Substances: Pharmacokinetic and Pharmacodynamic Data. In: <u>Prenatal Drug Exposure: Kinetics and Dynamics</u>. C. N. Chiang, C. Lee, eds., Research Monograph Series, National Institute on Drug Abuse, Vol. 60, 1985, pp. 110-147
- 3. Chiang, C.N. and Lee, C.S. eds.: <u>Prenatal Drug Exposure: Kinetics and Dynamics</u>. Research Monograph Series, National Institute on Drug Abuse, Vol. 60, 1985

Research articles

- 1. Lee, C.S. and Benet, L.Z.: Gas-liquid Chromatographic determination of ethambutol in plasma and urine of human and monkey. J. Chromatogr. 128: 188-192 (1976).
- 2. Lee, C.S., Gambertoglio, J.G., Brater, D.C., and Benet, L.Z.: Kinetics of oral ethambutol in the normal subjects. Clin. Pharmacol. Ther. 22: 615-621 (1977).
- 3. Lee, C.S. and Benet, L.Z.: Macro and micro determination of ethambutol in biological fluids. J. Pharm. Sci. 67: 470-473 (1978).
- 4. Lee, C.S., Marbury, T.C., Perrin, J.H., and Fuller, T.J.: Hemodialysis of theophylline in uremic patients. J. Clin. Pharmacol. 19: 219-226 (1979).
- 5. Lin, C.K., Lee, C.S., and Perrin, J.H.: Determination of two fenamates in plasma using high-performance liquid chromatography. J. Pharm. Sci. 69: 96-97 (1980).

- 6. Lee, C.S., Marbury, T.C., and Benet, L.Z.: Clearance calculations in hemodialysis:Application to blood, plasma, and dialysate measurements for ethambutol. J. Pharmacokinet. Biopharm. 8: 69-81 (1980).
- 7. Bruni, J., Wang, L., Marbury, T.C., Lee, C.S., and Wilder, B.J.: Protein binding of valproic acid in uremic patients. Neurol. 30: 557-559 (1980).
- 8. Marbury, T.C., Lee, C.S., Bruni, J., and Wilder, B.J.: The pharmacokinetics of valproic acid in patients with chronic renal failure during hemodialysis. Dialysis and Transplantation 9: 961-964 (1980).
- 9. Lee, C.S. and Wang, L.H.: An improved GLC method for the determination of ethambutol in biological fluids. J. Pharm. Sci. 69: 362-363 (1980).
- 10. Marbury, T.C., Wang, L.H., and Lee, C.S.: Hemodialysis of Acetaminophen in uremic patients. Int. J. Artificial Organs., 5: 263-266 (1980).
- 11. Imamura, I., Wang, L.H., Lee, C.S., and Perrin, J.H.: Effects of chlorpromazine and atropine on the gastrointestinal absorption of acetaminophen. Int. J. Pharmaceutics 5:25-32 (1980).
- 12. Wang, L.H., Lee, C.S., and Marbury, T.C.: Hemodialysis of mefenamic acid in uremia. Am. J. Hosp. Pharm. 37: 956-958 (1980).
- 13. Lee, C.S., Bruni, J., Marbury, T.C., Perchalski, R.J., and Wang, L.H.: Hemodialysis and total body elimination of carbamazepine during chronic hemodialysis. Clin. Toxicol. 17: 429-438 (1980).
- 14. Fleitman, J. S., Lee, C.S., and Perrin, J.H.: A rapid HPLC assay of benoxaprofen in plasma. J. Liq. Chromatogr. 3: 1165-1172 (1980).
- 15. Lee, C.S., Brater, D.C., Gambertoglio, J.G., and Benet, L.Z.: Disposition kinetics of ethambutol. J. Pharmacokinet. Biopharm. 8: 335-346 (1980).
- 16. Bruni J., Gallo, J.M., Lee, C.S., Perchalski, R.H., and Wilder, B.J.: Interactions of valproic acid with phenytoin. Neurology 30: 1233-1236 (1980).
- 17. Suber, R., Lee, C.S., Torosian, G., and Edds, G.: Comparison of the pharmacokinetics of sulfisoxazole in humans and two monogastric animal species. J. Pharm. Sci. 70: 981-984 (1981).
- 18. Wang. L.H., Lee, C.S., Marbury, T.C., and Majeske, B.: Clearance calculations in hemodialysis: Application to plasma, red blood cell, and dialysate measurement for cyclophosphamide. Clin. Pharmacol. Ther. 29: 365-372 (1981).
- 19. Imamura, I., Wang, L.H., Lee, C.S., and Perrin, J.H.: Acetaminophen- Diphenhydramine interaction in rabbits. Intl. J. Pharmaceutics 8: 277-284 (1981).
- 20. Salem, R.B., Wilder, B.J., Yost, R.L., Doering, P.L. and Lee, C.S.: Rapid infusion of phenytoin sodium loading doses. Am. J. Hosp. Pharm. 38: 354-357 (1981).
- 21. Lee, C.S., Marbury, T.C., Wang, L.H., and Cade, R.J.: Hemodialysis for acetaminophen detoxification. Clin. Toxicol. 18: 431-439 (1981).
- 22. Marbury, T.C., Lee, C.S., Perchalsky, R.J., Wang, L.H., and Wilder B.J.: Hemodialysis clearance of ethosuximide in end stage renal disease patients. Am. J. Hosp. Pharm. 38: 1757-1760 (1981).
- 23. Lee, C.S., Wang, L.H., Marbury, T.C., and Majeske, B.: Hemodialysis clearance of dyphylline in chronic hemodialysis patients, J. Pharmacol. Exp. Ther. 217: 340-344 (1981).
- 24. Lee, C.S.: The assessment of fractional drug removal by extracorporeal dialysis. Biopharm. Drug Disp. 3: 165- 173 (1982).
- 25. Lee, C.S. Marbury, T.C., and Perchalski, R.J.: Primidone pharmacokinetics in ESRD patients

- during hemodialysis treatment. J. Clin. Pharmacol. 22: 301-308 (1982).
- 26. Lee, C.S., and Marbury, T.C.: Calculation of peritoneal clearance theophylline as an example. Peritoneal Dialysis Bulletin 2: 193-194 (1982).
- 27. Marbury, T.C., Sheppard, J.D., Gibbons, K., and Lee, C.S.: Combined antidotal and hemodialysis treatments for nitroprusside-induced cyanide toxicity. Clin. Toxicol. 19: 475-482 (1982).
- 28. Chen, M.M., Lee, C.S., Imamura, Y., and Perrin J.H.: Acetaminophen- aluminum hydroxide interaction in rabbits. J. Pharm. Sci. 72: 828-830 (1983).
- 29. Faulkner, R.D., and Lee, C.S.: Comparative assays for doxepin and desmethyldoxepin using HPLC and HPTLC. J. Pharm. Sci. 72: 1165-1167 (1983).
- 30. Lee, C.S.: Pharmacokinetics of urea: Development of a kinetic model for correlating daily nitrogen intake and urea metabolism in chronic renal failure. Biopharm. Drug Disp. 4: 225-231 (1983).
- 31. Lee, C.S., Peterson, J., Marbury, T.C.: Comparative pharmacokinetics of theophylline in peritoneal dialysis and hemodialysis. J. Clin. Pharmacol. 23: 274-280 (1983).
- 32. Chen, M.M., Lee, C.S., and Perrin, J.H.: Absorption and disposition of ethambutol in rabbits. J. Pharm. Sci. 72: 828 (1983).
- 33. Senekjian, H.O., Lee, C.S., Kuo, T.S., Au, D.S., and Krothapalli, R.: Absorption and disposition of ibuprofen in hemodialyzed uremic patients. Eur. J. Rheumatol. Inflamm. 6: 155-162 (1983).
- 34. Faulkner, R., Pitts, W., Lee, C.S., Lewis, W., and Fann, W.: Multi-dose kinetics of doxepin in depressed patients. Clin. Pharmacol. Ther. 34: 509-515 (1983).
- 35. Varughese, A., and Lee, C.S.: Disposition kinetics of ranitidine in rats. Drugs under Exp. Clin. Res. 9: 837(1983).
- 36. Lee, C.S., and Marbury, T.C.: Drug therapy in hemodialysis patients clinical pharmacokinetic considerations. Clin. Pharmacokinet. 9: 42-66 (1984), Invited review article.
- 37. Au, D.S., Kuo, T.S., Mederski, B., and Lee, C.S.: Disposition kinetics of ibuprofen in nephrectomized dogs. J. Pharm. Sci. 73: 705 (1984).
- 38. Lee, C.S., and Varughese, A.: Dispostion kinetics of ethambutol in nephrectomized dogs. J. Pharm. Sci. 73: 787 (1984).
- 39. Faulkner, R.D., Senekjian, H.O., and Lee, C.S.: Hemodialysis of doxepin and desmethyldoxepin in uremic patients. Int. J. Artif. Organs 8: 151-155 (1984).
- 40. Chen, M.M., and Lee, C.S.: Cimetidine-acetaminophen interaction in man. J. Clin. Pharmacol. 25: 227-229 (1985).
- 41. Varughese, A., Brater, D.C., Benet, L.Z., and Lee, C.S.: Ethambutol Kinetics in patients with impaired renal function. Am. Rev. Resp. Dis. 134: 34-38 (1986).
- 42. Sun, X.S., Embil, K., Chow, D.S., and Lee, C.S.: HPLC analysis, protein binding, and red blood cell partition of phenprobamate. Biopharm. Drug Disposition 8: 341-351 (1987).
- 43. Sun, X.S., Embil, K., and Lee, C.S.: Time-dependent absorption of phenprobamate. Pharmaceutical Research 5: 387-390 (1988).
- 44. Karna, P., Lee, C., Kumar, A., Dyke, J., Gooch, W. M. Popualtion pharmacokinetics of ceftizoxime in premature newborns. Develop Pharmacol Ther 20: 135-143 (1993).
- 45. Jusko, W. J., Piekoszewski, W., Kilintman, G. B., Shaefer, M. S., Hebert, M. F., Piergies, A., Lee, C., Schechter, P., Mekki, Q. A. Pharmacokinetics of tacrolimus in liver transplant

- patients. Clin Pharmacol Ther 57: 281-290 (1995).
- 46. Shue, Y. K., Sears, P. S., Shangle, S., Walsh, R.B., Lee, C., Gorbach, S.L., Okumu, F., Preston, R.A. Safety, Tolerance and Pharmacokinetic Studies of OPT-80 in Healthy Volunteers Following Single and Multiple Oral Doses. Antimicrobial Agents and Chemotherapy 52: 11391-1395 (2008)
- 47. Lee, C. Drug Safety, Whose Issue Is It? The Journal of Taiwan Pharmacy 25(2): 3-6 (2009)
- 48. Lee, C. Clinical Trial, What Is It? The Journal of Taiwan Pharmacy, 25(3): 12-21 (2009)
- 49. Lee, C. The Next Wave of Blockbuster Diabetic Drugs, Jin-Fu Foundation, National Taiwan University Medical College, pp. 1-3, Feb, 2010
- 50. Lee, C. Tilting the Equilibrium of Pharmacist Supply and Demand. The Journal of Taiwan Pharmacy, 27(1): 10-16 (2011)
- 51. Lee, C. and Lubin, M. A Randomized, Double-Blind, Placebo Controlled, Four Week Study to Assess the Efficacy and Safety of Arthri-Zen Relief Herbal Dietary Supplement in Patients Experiencing Mild to Moderate Arthritis Pain (presented and submitted)

RESEARCH FUNDING

- 1. Starter Grant, University of Florida, 1978 (\$5,100) Enhanced Absorption of Water Sparingly Soluble Drugs
- 2. Key Pharmaceuticals, 1978 (\$6,000)
 Bioavailability of a sustained-release theophylline formulation
- 3. Pfizer, Inc. 1978-79 (\$40,000)
 - The Psychobiology of Doxepin in Depression (Co-Investigator, PI: Richard A. Moskovitz, MD)
- 4. Meyer Laboratories, 1978-79 (\$18,000)
 Bioavailability of a Sustained-Release Theophylline Formulation
- 5. Initiation Grant, University of Florida, 1979 (\$3,000)
 Pharmacokinetics of Valproic Acid in Chronic Renal Failure Patients during Hemodialysis
- 6. Department of Pediatrics, College of Medicine, University of Florida, 1979 (\$1,800) Therapeutic monitoring of Theophylline in Asthmatic Patients
- 7. Biomedical Research and Development Grant, HEW, 1978-80 (\$350,000) (Co-Investigator, PI: John H. Perrin, PhD)
 - i) Enhanced GI Absorption of Flufenamic Acid by beta- Cyclodextran Inclusion
 - ii) Disposition Kinetics of Drugs in Ascitis
- 8. Department of Gynecology and Obstetrics, College of Medicine, University of Florida, 1979 (\$6,200)
 - Determination of Urinary MHPG (3-methoxy 4-hydroxy phenyl- ethyleneglycol) in depressed Women
- 9. National Cancer Institute, NIH, 1979-80 (\$67,000) Effect of Intravenous Hyperalimentation on Cancer Chemotherapy (Co-Investigator, PI: Warren E. Ross, MD)
- 10. Glaxo Research Laboratories, 1980 (\$4,000) Pharmacokinetics of Ranitidine
- 11. American Lung Association, 1980 (\$15,000) Ethambutol Kinetics in Tuberculosis Patients with Renal Failure

- 12. Shand's Teaching Hospital, University of Florida, 1980 (\$1000)

 Therapeutic monitoring of Acetaminophen in Analgesia
- 13. New Research Opportunities Grant, University of Houston, 1981 (\$2,500) Pharmocokinetics of Clonidine in ESRD and Dialysis
- 14. Biomedical Research Supporting Grant, National Institute of Health, 1981 (\$25,000)

 Drug Kinetics of Constant Rate Intravenous Infusion
- 15. Department of Pediatrics, University of Texas Health Sciences Center at Houston, 1982 (\$3,000)
 - Therapeutic monitoring of Theophylline in Pediatric Patients
- 16. Department of Gastroenterology, University of Texas Health Sciences Center at Houston, 1982 (\$7,500)
 - Therapeutic monitoring of Cimetidine
- 17. Biomedical Research Supporting Grant, National Institute of Health, 1982 (\$3,000) Nitrogen Metabolism in Uremia
- 18. The Upjohn Company, 1983 (\$1000)

 Absorption and Disposition of Ibuprofen in Hemodialyzed Uremic Patients
- 19. Boots Pharmaceuticals, Inc., 1983 (\$30,000) Evaluation of Ibuprofen Sustained-Release Formulations
- 20. Internal Medicine, University of Texas Health Sciences Center at Houston, 1984 (\$1000) Pharmacokinetics of Ethambutol in Renal Failure
- 21. University of Houston, 1984 (\$16,200)
 HPLC Analysis of Phenprobamate in Biological Fluids
- 22. Siegfried Ltd., Zofingen, Switzerland, 1984 (\$74,000)

 Pharmacokinetics of Phenprobamate in Rats and Humans
- 23. National Institute on Drug Abuse, 1984 (\$54,210) IGP/Office of Health and Human Services
- 24. Embil Pharmaceuticals, Inc., Istanbul, Turkey, 1985 (\$20,000) Anxiolytic Effects of Phenprobamate
- 25. Quantum Pharmics, New York, NY, 1985 (\$2,500) Carbamazepine Bioequivalence - a feasibility study
- 26. Quantum Pharmics, New York, NY, 1985-86 (\$65,632) Doxepin Bioequivalence
- 27. University of Houston, Grant in Aid, 1986 (\$2000) Maternal-Fetal Transport of Drugs

RECENT PRESENTATIONS

Xuzhou Economic & Technological Development Office, Xuzhou, Jiangsu (May 7, 2012) Title: A combination formulation of Sildenafil and Nitric Oxide Supplement for Erectile Dysfunction

Shanghai Jiaotong University, School of Pharmacy (May 15, 2012)

Title: Pharmacists' Role in Clinical Research