CURRICULUM VITAE

NAME:

Jessie L.-S. Au



Jessie L-S Au, Pharm. D., Ph.D.

Distinguished University Professor

508 Riffe Building 496 W. 12 th Avenue Columbus, OH 43210

E-mail: <u>au.1@osu.edu</u>

Phone: (614) 292-4244 , Fax: (614) 688-3223

EDUCATION

Institution	Degree	Year	Field
School of Pharmacy	Pharm.D.	1972	Clinical Pharmacy
University of California			
San Francisco, CA			
Dept. of Pharmaceutical Chemistry University of California San Francisco, CA	Ph.D.	1980	Pharmaceutics
Dept. of Experimental Therapeutics Roswell Park Memorial Institute Buffalo, NY	Postdoctoral Fellow	1979-1980	Biochemical Pharmacology

RESEARCH INTERESTS AND PROGRAMMATIC GOALS

Development of effective treatments of solid tumors has been my career goal. Our group has thus far taken two of our discoveries through clinical evaluation (including a phase III study that yielded positive findings). The distinguishing feature of my work is the ability to plan and integrate studies in diverse disciplines, to drive the translation of laboratory findings to survival-extending cancer treatments. My research goal for the next five years is to develop multi-target combination therapy that can control cancer (solid tumors) as a chronic disease. My programmatic goal is to develop the field of translational therapeutics through integration of the following physical and biological scientific disciplines.

- biology and pharmacology (mechanisms of drug action and resistance, nature and extent of drug effect as a function of drug concentration and treatment time or pharmacodynamics)
- pathology and imaging (quantifying biological changes and drug effects on organ and suborgan levels)

- analytical chemistry and biochemistry (measurements of drug and protein levels)
- engineering (mass transfer and spatial distribution)
- mathematics and computation (modeling of kinetic processes on cellular, organ and whole system levels, computer software development)
- physical pharmacy and polymeric drug carriers (develop formulations to deliver small and large molecules, nano- and microparticles, to achieve the desired pharmacodynamic profiles in tumors)
- clinical oncology (phase I/II/III trials; use computational approaches to guide dose selection and modification in phase I trials and to predict outcomes of phase III trials; effect-based therapy development paradigm)

HONORS AND AWARDS

President Scholarship, 1971-1972; Edith Claypole-Joe Shoong Scholarship, 1976-1977; Patent Fund Award; NIH Predoctoral Fellow, 1977-1979, University of California San Francisco. Rho Chi National Graduate Scholarship, 1977-1978. Technology Transfer Award, International Union Against Cancer, 1981. New Investigator Research Award, NIH, 1982. Research Career Development Award, NIH, 1990. MERIT Award, NIH, 1992. University Distinguished Scholar Award, The Ohio State University, 1992. Dorothy M. Davis Chair of Cancer Research, The Ohio State University, 1992. Fellow, American Association of Pharmaceutical Scientists, 1992. Frank Duckworth Eminent Visiting Scholar, University of Florida, 1993. Joseph V. Swintosky Distinguished Lecturer, University of Kentucky, 1997. Distinguished University Professor, The Ohio State University, 1998. Fellow, American Association for the Advancement of Science, 1999. Distinguished Visiting Professor, National University of Singapore, 2000. Alumni Row, University of California San Francisco, 2000. PPDM Research Achievement Award, American Association of Pharmaceutical Scientists, 2004. Semi-Finalist, NIH Director's Pioneer Award, 2004, 2005

MEMBERSHIP

American Association of Cancer Research; American Association of Cancer Research Women in Cancer Research; American Association of Pharmaceutical Scientists; American Association for Advancement of Science

PROFESSIONAL EXPERIENCE

- Clinical Pharmacist: Staff/Supervisor, Presbyterian Hospital of Pacific Medical Center, San Francisco, CA, 1972-1975; Volunteer pharmacist, Haight-Ashbury Free Medical Clinics, San Francisco, CA, 1977.
- Research Affiliate III, 1979-1980; Cancer Research Scientist I and II, Roswell Park Memorial Institute, Buffalo, NY, 1980-1983
- Assistant Professor, Division of Pharmaceutics and Pharmaceutical Chemistry, College of Pharmacy, The Ohio State University, 1983-1989
- Associate Professor, Division of Pharmaceutics and Pharmaceutical Chemistry, College of pharmacy, The Ohio State University, 1989-1992.
- Professor, Colleges of Pharmacy and Medicine, The Ohio State University, 1992-present
- Dorothy M. Davis Chair in Cancer Research, The Ohio State University, 1992-2004.
- Distinguished University Professor, Colleges of Pharmacy, Medicine and Engineering, The Ohio State University, 1998-present (life time appointment).
- Member, OSU Comprehensive Cancer Center, 1983-present.
- Member, Cancer Pharmacology Program, Institute of Biomedical Sciences Academic Sinica, Taipei, Taiwan, 1988-1993.
- Acting Co-Director, Developmental Therapeutics Program, OSU Comprehensive Cancer Center, 1991-1992.

Co-Director, Head and Neck Oncology Program, OSU Comprehensive Cancer Center, 1992-1993.

Co-Director, Urologic Oncology Program, OSU Comprehensive Cancer Center, 1992-1999. Director of Translational Research, OSU Comprehensive Cancer Center, 1993-1994. Deputy Director, OSU Comprehensive Cancer Center, 1994-1997.

ADMINISTRATIVE EXPERIENCE

I have experience in leading a relatively large research laboratory (**1** research personnel) and large-scale collaborative research projects in the U.S., Canada and Europe. Through my various administration positions in the Comprehensive Cancer Center and appointments to university level committees including the budget restructuring committee, I have also acquired significant experience in administration. As Deputy Director of the Comprehensive Cancer Center with **1** members drawn from 11 colleges, I was responsible for the preparation and defense of the NCI Cancer Center Core Grant and its expenditure (>\$3 M/yr), and budgeting and expending discretionary funds from the Cancer Hospital, the assignment of cancer center space (**1** to **1**), and the strategic and programmatic planning.

PROFESSIONAL SERVICE (National and International)

- Participant in the International Cancer Research Technology Transfer Program sponsored by the International Union Against Cancer, 1982
- Reviewer for Cancer Research, Cancer Chemotherapy and Pharmacology, Analytical Biochemistry, Pharmaceutical Research, Journal of Pharmaceutical Sciences, In vitro, Journal of National Cancer Institute, Biopharmaceutics and Drug Disposition, Journal of Drug Targeting, Journal of Chromatography, Oncogene, Clinical Cancer Research, PharmSci, Journal of Controlled Release, Journal of Pharmacology and Experimental Therapeutics, Biochemical Pharmacology, Nature Biotechnology

Member, NCI Program Project Grant Site Visit Team, 1983, 1992, 1993, 1998-2002

Member, NIH Experimental Therapeutics II Study Section, 1987-1992; NIH Small Business Innovative Research Study Section, 1987-1990; NIH AIDS and Related Research Review Group, 1989; NIH Pediatric AIDS Clinical Trial Study Section, 1993; NIH Alternative Medicine Study Section, 1993; NIH Pharmacology Study Section, 1994-96; NIH Experimental Therapeutic II Study Section, 1997; NCI Manpower (Training Grants) Study Section, 1997; NCI Cancer Center Support Grant Review Committee, 1997, 1998; NIH Developmental Therapeutics Study Section, 2002-2005

- Chair, Experimental Therapeutic II Special Study Section, 1996, 1997
- Member, U.S. Army Medical R & D Command Breast Cancer Research Program Review Group, 1994, 1997
- Member, Oncology Boundary Advisory Committee, NIH, 2001-2003 (responsible for realignment of oncology-related study sections which took place in 2003)
- Member, NCI Scientific Review Group Translational and Clinical Subcommittee D, 2001 2003.
- Member, Katholieke Universiteit Leuven, Research Grant Application Evaluation Committee, 2002; Reviewer, Research grants for Fonds zur Forderung, Der Weissenchaftsfonds. Austria, 2004
- Member, Arizona Disease Control Research Commission Review Panel, 1997-2002
- Ad hoc Member, Board of Scientific Counselors, National Center for Research Resources, Review of Biomedical Engineering and Instrumentation Program, 1996
- Chairperson, AAPS Annual Meeting Symposia, 1992, 2001

Member, Editorial Advisory Board, Pharmaceutical Research, 1990-present

- Member, Editorial Advisory Board, PharmSci (AAPS Journal), 1998-present
- Member, American Association of College of Pharmacy Graduate Affairs Committee, 1992 and 1993
- Chair (1993-1994) & Member (1994-1995), American Association of College of Pharmacy Paul Dawson Biotechnology Award Committee
- Member, American Association of Pharmaceutical Scientists: Task Force on Alternative Sources of Revenue, 1995-1996; Bylaw Committee, 1995-1997
- Member, NCI Strategy Planning Meeting on Intraperitoneal Cisplatin and Paclitaxel in ovarian Cancer, 1995
- External Reviewer of academic programs and faculty, University of Utah, University of Georgia, University of Michigan, University of Alabama, SUNY Stony Brook, University of Singapore, National Health Research Institute (Taiwan)
- Scientific Advisor, University of Pittsburgh Cancer Institute, 1997-1998; Roswell Park Cancer Institute, 1998-2001
- Member, American Association of Cancer Research Program Committee, 1997, 1998, 2001.
- Scientific Advisory Board, National Cancer Institute/Controlled Release Society International Symposium on Tumor Targeted Delivery Systems, 2000
- Member, NCI Gynecologic Oncology Group Retreat, May, 2000
- Member, NCI State of the Science Meeting on Lung Cancer, June, 2000
- Member, NCI State of the Science Meeting on Bladder Cancer, September, 2000
- Member, Scientific Program Committee, EORTC-NCI-AACR 2002 Symposium on Molecular Targets and Cancer Therapeutics, Frankfurt, Germany, 2002
- Chairperson, Electorate Nominating Committee, Pharmaceutical Sciences, American Association for the Advancement of Science (AAAS), 2001-2002
- Member-at-Large, AAAS Pharmaceutical Section, 2003–2006
- Member, Program Committee, Co-Chair on Symposium on Growth factor receptors and beyond. Second Pharmaceutical Sciences World Congress, Kyoto, Japan, 2004.
- Member, External Advisory Committee, Oklahoma Biomedical Research Infrastructure Network (BRIN) Program IdeA Networks for Biomedical Research Excellence (INBRE), 2004-2006.
- Reviewer, Cancer Research UK, 2004, 2005
- Chair, AAPS PPDM Hot Topics Committee (FDA Critical Path), 2004, 2005
- Review Committee, Science Foundation Ireland, 2006.
- Member, Program Committee; Convener, Symposium on Molecular Targeting in Cancer
 - Chemotherapy, Third Pharmaceutical Sciences World Congress, Amsterdam, Netherlands, 2007

ADMINISTRATIVE SERVICE: COLLEGE AND UNIVERSITY COMMITTEES

College

Member, College Curriculum subcommittee, 1985-1988

Member, College Admissions Committee, 1985-1988

Member, College Honors and Undergraduate Research Committee, 1985-1988

Faculty Advisor to the Kappa Epsilon Sorority, 1986-1989

Member, College Affirmative Action Committee, 1989-1990

Member/Chair, Search Committees for 4 faculty positions in Pharmaceutics Division, 1988-1990, 1993-94

Counselor, American Association of Colleges of Pharmacy Minority Research Program, 1989-1991 Chair, Honors Committee, 1996-1997

Member, Graduate and Research Committee, College of Pharmacy, 1984-1985, 1989-1999.

Member, Search Committee for Associate Dean, 1998-2000

Member, Search Committee for Director of Drug Delivery, 1999-2001

Comprehensive Cancer Center

Member, Search Committee for Director of Developmental Therapeutics Program of OSU Comprehensive Cancer Center, 1990-1992 Member, CCC/CHRI Strategic Planning Committee, 1992-1994 Member, CCC/CHRI Space Committee, 1992-1994 Chair, CCC Translational Research Committee, 1994-1997 Chair, CCC/CHRI Space Committee, 1994-1997 Chair, CCC/CHRI Shared Services Directors, 1994-1997 Chair, CCC Block Award Committee, 1994-1997 Chair, CCC/CHRI Drug Development Group, 1995-1997 Chair, American Cancer Society Institutional Grant Committee, 1995-1997 Chair, CCC/CHRI Development Grant Committee, 1995-1997 Member, CCC/CHRI Disease Specific Committee, 1992-1997 Member, CCC/CHRI Basic Science Committee, 1993-1997 Member, CCC/CHRI Executive Committee, 1994-1997 Member, CCC Human Cancer Genetics Search Committee, 1994-1997 Member, CCC/CHRI Institutional Biosafety/Etiologic Agents Committee, 1994-1997 Member, Office of Health Services Space Committee, 1994-1997 Member, The Interdisciplinary Research Center Directors Forum, 1994-1997 Member, CCC Program Directors Committee, 1994-1997 Co-Director, Drug Development Service, 1996-1998

<u>University</u>

Reviewer for University Interdisciplinary Research Grants and American Cancer Society Starter Grants, 1989-1994

Member, University Distinguished Scholar Award Selection Committee, 1992-1994

Alternate Member, Research and Graduate Council, 1993-1995 Member, Health Sciences Research Advisory Committee, 1994-1995 Alternate Member, Faculty Council, 1995-1997 Member, Provost's Advisory Committee, 1994-1997 Member, Provost's Council on International Affairs, 1994-1996 Member, Distinguished University Professor Selection Committee, 1996, 2000 Member, Academic Enrichment Program Selection Committee, 1996, 1997 Alternate Member, University Senate, 1991-1994, 1995-1997 Ad Hoc Member, Industry and Technology Council of Central Ohio Leadership Committee, 1994-97 Member, Council on Academic Excellence for Women, 1995-1998 Member, University Central Budget Allocation Committee, 1996-1998 Member, Oversight Committee for International Affairs, 1996-1999 Member, President and Provost Advisory Council, OSU, 1998 (lifetime appointment) Member, Scientific Advisory Committee, NSF Mathematical Bioscience Institute, 2000-present Member or Chair, Selection Committee for Distinguished University Professors and Distinguished University Lecturer, 1996, 1997, 2000, 2002, 2003 **PUBLICATIONS**

- 1. Wu, A.T., Au, J.L.-S., and Sadee, W. Hydroxylated metabolites of R,S-1-(tetrahydro-2-furanyl)-5-fluorouracil in rats and rabbits. Cancer Res., 38:210-214, 1978.
- Au, J.L.-S., Wu, A.T., Friedman, M.A., and Sadee W. Pharmacokinetics and metabolism of ftorafur (R,S-1-(tetrahydro-2-furanyl)-5-fluorouracil) in man. Cancer Treat. Rep., 63:343-350, 1979.
- 3. Au, J.L.-S. and Sadee W. 5-Fluorouracil concentrations in human plasma following R,S-1-(tetrahydro-2-furanyl)-5-fluorouracil (ftorafur) administration. Cancer Res., 39:4289-4290, 1979.
- 4. Au, J.L.-S. and Sadee W. Activation of ftorafur (R,S-1-(tetrahydro-2-furanyl)-5-fluorouracil) to fluorouracil and (-butyrolactone. Cancer Res., 40:2814-2819, 1980.
- 5. Au, J.L.-S. and Sadee, W. Stereoselective metabolism of ftorafur (R,S-(1-tetrahydro-s-furanyl)-5-fluorouracil). Cancer Chemotherap. Pharmacol., 7:55-59, 1981.
- 6. Au, J.L.-S., Wientjes, M.G., Luccioni, C., and Rustum, Y.M. Reversed phase ion-pair high pressure liquid chromatographic assay of 5-fluorouracil, 5'-deoxy-f-fluorouridine, their nucleosides, mono-,di-, and triphosphate nucleotides with a mixture of quaternary ammonium ions. J. Chromatogr., 228:245-256, 1982.
- 7. Au, J.L.-S., Rustum, Y.M., Mittelman, A., Ledesma, E., and Creaven, P.J. Clinical pharmacological studies of concurrent infusion of 5-fluorouracil and thymidine in the treatment of colorectal adenocarcinoma. Cancer Res., 42:2930-2937, 1982.
- 8. Rustum, Y.M., Danhauser, L.L., Luccioni, C., and Au, J.L.-S. Determinants of response to antimetabolites and their modulation by normal purine and pyrimidine metabolites. Cancer Treat. Rep., 65 (Supp. 3):73-82, 1982.
- 9. Au, J.L.-S., Rustum, Y.M., Minowada, J., and Srivastava, B.I.S. Differential selectivity of 5fluorouracil and 5'-deoxy- 5-fluorouridine in cultured human B lymphocytes and mouse L1210 leukemia. Biochem. Pharmacol., 32:541-546, 1983.
- 10. Au, J.L.-S., Walker, J.S., and Rustum, Y.M. Pharmacokinetic studies of 5-fluorouracil and 5'deoxy-5-fluorouridine in rats. J. Pharmacol. Exper. Therap., 227:174-180, 1983.
- 11. Steinberg, A., Petrelli, N.J., Mittelman, A., Rustum, Y.M., Au, J.L.-S., and Creaven, P. A combination of 5-fluorouracil and thymidine in advanced colorectal carcinoma. Cancer Chemotherap. Pharmacol., 13:218-222, 1984.
- 12. Au, J.L.-S. Effect of age on the disposition and tissue clearances of 5-fluorouracil and 5'-deoxy-5-fluorouridine. Pharm. Res., 6:279-284, 1985.

- Trave, F., Cannobio, L., Au, J.L.-S., and Rustum, Y.M. Role of administration on the therapeutic efficacy of 5-fluorouracil and 5'-deoxy-5-fluorouridine. J. Natl. Cancer Inst., 78:527-532, 1987.
- 14. Au, J.L.-S., Su, M-H., and Wientjes, M.G. Isocratic ion-pair reversed-phase high performance liquid chromatographic analysis of adenylate nucleotides. J. Chromatogr., 423:308-312, 1987.
- 15. Au, J.L.-S. Disposition and availability of the 5-fluorouracil prodrug 5'-deoxy- 5-fluorouridine after oral administration in rats. J. Pharm. Sci., 76:699-702, 1987.
- 16. Wientjes, M.G. and Au, J.L.-S. Inhibition of intestinal pyrimidine nucleoside phosphorylases. Pharm. Res., 4:425-428, 1987.
- 17. Au, J.L.-S., Rustum, Y.M., and Slocum, H.K. Biological activities of 5-fluorouracil and its prodrug 5'-deoxy-5-fluorouridine in rats. Cancer Drug Delivery, 4:137-144, 1987.
- 18. Au, J.L.-S., Bramer, S.L., and Wientjes, M.G. Effect of uridine coadministration on 5'-deoxy-5-fluorouridine disposition in rats. Cancer Chemother. Pharmacol., 22:5-10, 1988.
- 19. Bramer, S.L., Gunnarsson, L., and Au, J.L.-S. Biologic activity of 5'-deoxy- 5-fluorouridine by rectal administration. Pharm. Res., 6:318-322, 1989.
- 20. Au, J.L.-S. and Gunnarsson, L. Absorption of 5'-deoxy-5-fluorouridine from colon. Pharm. Res., 6:323-327, 1989.
- 21. Au, J.L.-S., Su, M-H., and Wientjes, M.G. Acetonitrile extraction of intracellular nucleosides and nucleotides. Clin. Chem., 35:48-51, 1989.
- 22. Dalton, J.T., Geuns, E., and Au, J.L.-S. High performance liquid chromatographic analysis of mitomycin C in rat and human plasma and urine. J. Chromatogr., 495:330-337, 1989.
- 23. Schmittgen, T.D., Au, J.L.-S., Wientjes, M.G., Badalament, R.A., and Drago, J.R. Cultured human bladder tumors for pharmacodynamic studies. J. Urol., 145:203-207, 1991.
- 24. Wientjes, M.G., Dalton, J.T., Badalament, R.A., Drago, J.R., Dasani, B.M., and Au, J.L.-S. A method to study drug concentration-depth profiles in tissues: Mitomycin C in dog bladder wall. Pharm. Res., 8:168-173, 1991.
- 25. Au, J.L.-S., Dalton, J.T., and Wientjes, M.G. Evidence of significant absorption of sodium salicylate from urinary bladders of rats. J. Pharmacol. Exper. Therap., 258:357-364, 1991.
- 26. Wientjes, M.G. and Au, J.L.-S. High performance liquid chromatographic analysis of 2',3'-dideoxyinosine in biological samples. J. Chromatogr., 563:400-406, 1991.
- 27. Schmittgen, T.D., Wientjes, M.G., Badalament, R.A., and Au, J.L.-S. Pharmacodynamics of mitomycin C in cultured human bladder tumors. Cancer Res., 51:3849-3856, 1991.

- 28. Wientjes, M.G., Dalton, J.T., Badalament, R.A., Drago, J.R., and Au, J.L.-S. Bladder wall penetration of intravesical mitomycin C in dogs. Cancer Res., 51:4347-4354, 1991.
- 29. Dalton, J.T., Wientjes, M.G., Badalament, R.A., Drago, J.R., and Au, J.L.-S. Pharmacokinetics of intravesical mitomycin C in superficial bladder cancer patients. Cancer Res., 51:5144-5152, 1991.
- 30. Dalton, J.T., Harrington, M., and Au, J.L.-S. Evidence of significant absorption of antipyrine from urinary bladders of rats. J. Pharmacol. Exper. Therap., 260:608-613, 1992.
- Schmittgen, T.D., Koolemans-Beynen, A., Webb, T.E., Rosol, T.J., and Au, J.L.-S. Effects of 5fluorouracil, leucovorin and glucurate in rat colon tumor explants. Cancer Chemother. Pharmacol., 30:25-30, 1992.
- 32. Wientjes, M.G. and Au, J.L.-S. Pharmacokinetics of oral 2',3'-dideoxyinosine in rats. Pharm. Res., 9:822-825, 1992.
- 33. Wientjes, M.G. and Au, J.L.-S. Lack of pharmacokinetic interaction between 2',3'dideoxyinosine and 3'-azido-3'-deoxythymidine in rats. Antimicrob. Agents Chemother., 36:665-668, 1992.
- 34. Wientjes, M.G., Mukherji, E.M., and Au, J.L.-S. Nonlinear disposition of intravenous 2',3'dideoxyinosine in rats. Pharm. Res., 9:1070-1075, 1992.
- 35. Bramer, S.L., Wientjes, M.G., and Au, J.L.-S. Absorption of 2',3'-dideoxyinosine from lower gastrointestinal tract in rats and kinetic evidence of different absorption rates in colon and rectum. Pharm. Res., 10:763-770, 1993.
- 36. Bramer, S.L., Wientjes, M.G., and Au, J.L.-S. Gastrointestinal and hepatic first pass elimination of 2',3'-dideoxyinosine in rats. J. Pharmacol. Exper. Therap., 265:731-738, 1993.
- 37. Dalton, J.T. and Au, J.L.-S. 2',3'-dideoxyinosine is not metabolized in human placenta. Drug Metab. Disp., 21:544-546, 1993.
- 38. Wientjes, M.G., Badalament, R.A., Wang, R.C., Hassan, F., and Au, J.L.-S. Penetration of mitomycin C in human bladder. Cancer Res., 53:3314-3320, 1993.
- 39. Wientjes, M.G., Badalament, R.A., and Au, J.L.-S. Use of pharmacologic data and computer simulations to design an efficacy trial of intravesical treatment for superficial bladder cancer. Cancer Chemother. Pharmacol., 32:255-262, 1993.
- 40. Au, J.L.-S., Wientjes, M.G., Rosol, T.J., Koolemans-Beynen, A., Goebel, E.A., and Schuller, D.E. Histocultures of patient head and neck tumors for pharmacodynamic studies. Pharm. Res., 10:1493-1499, 1993.
- 41. Yeh, T.-K., Dalton, J.T., and Au, J.L.-S. High performance liquid chromatographic determination of pentamidine in plasma. J. Chromatogr., 622:255-261, 1993.

- 42. Schmittgen, T.D., Weaver, J.M., Badalament, R.A., Wientjes, M.G., Klein, E., Young, D., and Au, J.L.-S. Correlation of human bladder tumor histoculture proliferation and sensitivity to mitomycin C with tumor pathobiology. J. Urol., 152:1632-1636, 1994.
- 43. Mukherji, E., Millenbaugh, N., and Au, J.L.-S. Percutaneous absorption of 2',3'-dideoxyinosine in rats. Pharm. Res., 11:809-815, 1994.
- 44. Chai, M.-F., Wientjes, M.G., Badalament, R.A., Burgers, J.K., and Au, J.L.-S. Pharmacokinetics of intravesical doxorubicin in superficial bladder cancer patients. J. Urol., 152:374-378, 1994.
- 45. Mukherji, E., Au, J.L.-S., and Mathes, L.E. Differential antiviral activity and intracellular metabolism of 3'-azido-3'-deoxythymidine and 2',3'-dideoxyinosine in human cells. Antimicrob. Agents Chemother., 38:1573-1579, 1994.
- 46. Kang, H.-J.K., Wientjes, M.G., and Au, J.L.-S. Tissue pharmacokinetics of 2',3'-dideoxyinosine in rats. Biochem. Pharmacol., 48:2109-2116, 1994.
- 47. Dalton, J.T., Wientjes, M.G., and Au, J.L.-S. Effect of bladder resorption on pharmacokinetic data analysis. J. Pharmacokin. Biopharm., 22:183-205, 1994.
- 48. Gao, X., Buffington, C.A., and Au, J.L.-S. Effect of interstitial cystitis on drug absorption from urinary bladder. J. Pharmacol. Exper. Therap., 271:818-823, 1994.
- 49. Gupta, E., Wientjes, M.G., and Au, J.L.-S. Penetration kinetics of 2',3'-dideoxyinosine in dermis is described by the distributed model. Pharm. Res., 12:108-112, 1995.
- 50. Wientjes, M.G., Pretlow, T.G., Badalament, R.A., Burgers, J.K., and Au, J.L.-S. Histocultures of human prostate tissues for pharmacologic evaluation. J. Urol., 153:1299-1302, 1995.
- 51. Song, D. and Au, J.L.-S. Isocratic high performance liquid chromatographic assay of taxol in biological fluids and tissues using automated column switching. J. Chromatogr., 663:337-344, 1995.
- 52. Kalns, J.E., Millenbaugh, N.E., Wientjes, M.G., and Au, J.L.-S. Design and analysis of in vitro antitumor pharmacodynamic studies. Cancer Res., 55:5315-5322, 1995.
- 53. Gao, X., Wientjes, M.G., and Au, J.L.-S. Use of drug kinetics in dermis to predict in vivo blood concentration after topical application. Pharm. Res., 12:2012-2017, 1995.
- 54. Gao, X., Wientjes, M.G., and Au, J.L.-S. Extensive absorption of 2',3'-dideoxyinosine by intratracheal administration in rats. Pharm. Res., 12:1901-1906, 1995.
- 55. Wientjes, M.G., Badalament, R.A., and Au, J.L.-S. Penetration of intravesical doxorubicin in human bladders. Cancer Chemother. Pharmacol., 37:539-546, 1996.
- 56. Yeh, T.-K., Kang, H.-J., Wientjes, M.G., and Au, J.L.-S. Pharmacokinetic interaction of 2',3'dideoxyinosine and pentamidine in rats. Pharm. Res., 13:626-630, 1996.

- 57. Song, D. and Au, J.L.-S. Direct injection isocratic high-performance liquid chromatographic analysis of mitomycin C in plasma. J. Chromatogr., 676:165-168, 1996.
- 58. Song, D., Hsu, L.-F., and Au, J.L.-S. Binding of taxol to plastic and glass containers and protein under in vitro conditions. J. Pharm. Sci., 85:29-31, 1996.
- 59. Gan, Y., Wientjes, M.G., Schuller, D.E., and Au, J.L.-S. Pharmacodynamics of taxol in human head and neck tumors. Cancer Res., 56:2086-2093, 1996.
- 60. Gan, Y., Wientjes, M.G., Badalament, R.A., and Au, J.L.-S. Pharmacodynamics of doxorubicin in human bladder tumors. Clin. Cancer Res., 2:1275-1283, 1996.
- 61. Yen, W.-C., Wientjes, M.G., and Au, J.L.-S. Differential effect of taxol in rat primary and metastatic prostate tumors: site-dependent pharmacodynamics. Pharm. Res., 13:1305-1312, 1996.
- 62. Yen, W.C., Schmittgen, T.S., and Au, J.L.-S. Different pH dependency of mitomycin C activity in monolayer and 3-dimensional cultures. Pharm. Res., 13:1887-1891, 1996.
- 63. Song, D., Wientjes, M.G., and Au, J.L.-S. Isocratic high-performance liquid chromatographic determination of thiacetazone by direct injection of plasma into an internal surface reversed-phase column. J. Chromatogr., 690:289-294, 1997.
- 64. Weaver, J.R. and Au, J.L.-S. Comparative scoring by visual and image analysis of cells in human solid tumors labeled for proliferation markers. Cytometry, 27:189-199, 1997.
- 65. Yen, W.-C. and Au, J.L.-S. Pharmacodynamic evaluation of mitomycin C analog BMS-181174 for potential use in intravesical bladder cancer therapy. Pharm. Res., 14:241-245, 1997.
- 66. Kang, H.-J. K., Wientjes, M.G., and Au, J.L.-S. Physiologically based pharmacokinetic models of 2',3'-dideoxyinosine. Pharm. Res., 14:337-344, 1997.
- 67. Schuller, D.E., Grecula, J.C., Gahbauer, R.A., Bauer, C., Au, J.L.-S., Smith, R.E., Haller, J.R., Mountain, R.E., Young, D.C., and Nag, S. Intensified regimen for advanced head and neck squamous cell carcinomas. Arch. Otolaryngol. Head Neck Surg., 123:139-144, 1997.
- 68. Chen, C.T., Au, J.L.-S., Gan, Y., and Wientjes, M.G. Differential time dependency of antiproliferative and apoptotic effects of taxol in human prostate tumors. Urol. Onc., 3:11-17, 1997.
- 69. Song, D., Wientjes, M.G., and Au, J.L.-S. Bladder tissue pharmacokinetics of intravesical taxol. Cancer Chemother. Pharmacol., 40:285-292, 1997.
- 70. Weaver, J.R. and Au, J.L.-S. Application of automatic thresholding in image analysis scoring of cells in human solid tumors labeled for proliferation markers. Cytometry, 29:128-135, 1997.
- 71. Song, D., Wientjes, M.G., Gan, Y., and Au, J.L.-S. Bladder tissue pharmacokinetics and antitumor effect of intravesical 5-fluorouridine. Clin. Cancer Res., 3:901-909, 1997.

- 72. Au, J.L.-S., Kalns, J., Gan, Y., and Wientjes, M.G. Pharmacologic effects of taxol in human bladder tumors. Cancer Chemother. Pharmacol., 41:69-74, 1997.
- 73. Millenbaugh, N.J., Gan, Y., and Au, J.L.-S. Cytostatic and apoptotic effects of paclitaxel in human ovarian tumors. Pharm. Res., 13:123-138, 1998.
- Gao, X., Au, J.L.-S., Badalament, R.A., and Wientjes, M.G. Bladder tissue uptake of mitomycin C during intravesical therapy is linear with drug concentration in urine. Clin. Cancer Res., 4:139-143, 1998.
- 75. Chen, C.T., Au, J.L.-S., and Wientjes, M.G. Pharmacodynamics of doxorubicin in human prostate tumors. Clin. Cancer Res., 4:277-282, 1998.
- 76. Gan, Y., Lu, J., and Au, J.L.-S. Cytostatic and apoptotic effects of paclitaxel in human breast tumors. Cancer Chemother. Pharmacol., 42:177-183, 1998.
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- 211. Hu, X., Au, J.L.-S. and Wientjes, M.G. Implantable mini-cylinders for regional paclitaxel delivery. AAPS PharmSci Vol. 5, 2003.
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- 215. Xin, Y., Chen, D., Song, S-H., Lyness, G., Wientjes, M.G. and Au, J.L.-S. Low-does suramin enhances antitumor activity of mitomycin C in bladder tumors. Proc. Amer. Assoc. Cancer

Res. 45:461, 2004.

- 216. Hu, X.S., Koserek, C.E., Couto, C.G., Chen, D., Kisseberth, W.C., Wientjes, M.G. and Au, J.L.-S. Population pharmacokinetics of low dose suramin as a chemosensitizer in pet dogs with naturally occurring tumors. Proc. Amer. Assoc. Cancer Res. 45:461, 2004.
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- 219. Wientjes, M.G, Zheng, J., Hu, L., Gan, Y., Au, J.L.-S. Intraprostatic chemotherapy: kinetics Kinetics and mechanisms of doxorubicin transport. Proc. Amer. Assoc. Pharmaceut. Sci.,Doxorubicin Transport. AAPS PharmSci Vol. 6: W5330, 2004.
- Hu, X., Au, J.L-S, Wientjes, M.G. Tissue distribution of intravenous low dose suramin in tumor-bearing mice. Proc. Amer. Assoc. Pharmaceut. Sci., AAPS PharmSci Vol. 6: W5331, 2004.
- 221. Lu, Z., Wientjes, T., Au, J.L.-S. Nontoxic suramin treatments enhance docetaxel activity in chemotherapy-pretreated nonsmall cell lung xenograft tumors. Proc. Amer. Assoc. Cancer Res., 46:4994, 2005.
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- 223. Hu, L., Zhao, L., Chen, D., Hu, X., Wang, J., Au, J.L.-S., Wientjes, M.G. Physiologically based pharmacokinetic study on suramin. Proc. Amer. Assoc. Cancer Res., 46:3991. 2005.

PATENTS AWARDED

- 1. Methods for treating superficial bladder carcinoma. J.L.-S. Au and M.G. Wientjes. US Patent No. 6,286,513 B1. 9/11/01.
- 2. Methods and compositions for modulating cell proliferation and cell death. J.L.-S. Au and M.G. Wientjes. US Patent No. 6,599,912 B1. 7/29/03.
- 3. Methods and compositions for modulating cell proliferation and cell death. J.L.-S. Au and M.G. Wientjes. Singapore Patent, 2004.

- 4. Methods and compositions for modulating cell proliferation and cell death. J.L.-S. Au and M.G. Wientjes. Australia Patent, 2004.
- 5. Methods and compositions for enhancing delivery of therapeutic agents to tissues. J.L.-S. Au and M.G. Wientjes. Australia Patent No. 777620, 2005.
- 6. Methods and composition for modulating drug activity through telomere damage. J.L.-S. Au and M.G. Wientjes. US Patent. 2/7/06.

INVITED LECTURES AND SYMPOSIUM PRESENTATIONS

- 1. Pharmacokinetics and metabolism of Ftorafur. Division of Cancer Treatment, National Cancer Institute, NIH, March, 1979.
- 2. Pharmacokinetics and metabolism of Ftorafur. Department of Pharmacology, George Washington University, March, 1979.
- 3. Pharmacokinetics and metabolism of Ftorafur. Department of Experimental Therapeutics, Roswell Park Memorial Institute, March, 1979.
- 4. Pharmacokinetics and metabolism of Ftorafur. Comprehensive Cancer Center, University of Southern California, May, 1979.
- 5. Biochemical and clinical pharmacology of 5-fluorouracil and its derivatives. Anthony Van Leeuwenhoekhuis, Nederlands Kanker Institute, Amsterdam, The Netherlands, August, 1981.
- 6. Pharmacokinetic determinants of tissue selectivity of metabolic prodrugs. State University of New York at Buffalo, 1982.
- 7. Clinical and biochemical pharmacology of fluorinated pyrimidines. Department of Pharmacology, Medical College of Wisconsin, 1982.
- 8. Clinical and biochemical pharmacology of fluorinated pyrimidines. Children's Hospital, University of Southern California, 1982.
- 9. Clinical and biochemical pharmacology of fluorinated pyrimidines. College of Pharmacy, University of Kentucky, 1982.
- 10. Clinical and biochemical pharmacology of fluorinated pyrimidines. College of Pharmacy, Ohio State University, 1982.
- 11. Pharmacologic and pharmacokinetic aspects of 5'-dFUR therapy. F. Hoffmann-LaRoche Inc., Basel, Switzerland, 1983.
- 12. Therapeutic selectivity of 5'-deoxy-5-fluorouridine. French Association for the Study of Cancer, Paris, France, 1983. (Symposium speaker).

- 13. Comparative pharmacological studies of 5-fluorouracil and 5'-deoxy-5-fluorouridine in rats. F. Hoffman-LaRoche Inc., Basel, Switzerland, 1985.
- 14. Biological activity and pharmacology of 5'-deoxy-5-fluorouridine. Hoffman-LaRoche Inc., Nutley, New Jersey, 1985.
- 15. Intestinal crypt cells for pharmacodynamic and toxicokinetic studies. University of Michigan, November, 1987.
- 16. Pharmacodynamics of anticancer drugs. Washington State University, March, 1987.
- 17. Cultured intestinal crypt cells for pharmacodynamic and toxicokinetic studies. Merck, Sharp and Dohme Research Laboratories, West Point, PA, 1987.
- 18. Approaches to improve the therapeutic efficacy of fluorinated pyrimidines. Department of Pharmaceutics, University of Southern California, June, 1987.
- 19. Pharmacodynamics of intravesical mitomycin C. Leiden University, Leiden, The Netherlands, August, 1990.
- 20. Pharmacokinetics and pharmacodynamics of intravesical mitomycin C. Merck, Sharp and Dohme Research Laboratories, Blue Bell, PA, October, 1990.
- 21. Pharmacokinetics and pharmacodynamics of intravesical mitomycin C. Merck, Sharp and Dohme Research Laboratories, West Point, PA, November, 1990.
- 22. Pharmacology of intravesical Mitomycin C therapy for bladder cancer. Cleveland Clinic Foundation, January, 1991.
- 23. Pharmacokinetics and pharmacodynamics of intravesical mitomycin C for bladder cancer. Children's Hospital, Columbus, Ohio, March, 1991.
- 24. Pharmacodynamics and metabolism of Ftorafur. Department of Medical Oncology, University of Southern California, March, 1991.
- 25. Pharmacokinetics and pharmacodynamics of intravesical mitomycin C for bladder cancer. Department of Pharmaceutics, University of Southern California, April, 1991.
- 26. Pharmacokinetics and pharmacodynamics of intravesical mitomycin C for bladder cancer. Southwest Oncology Meeting, April, 1991 (symposium speaker).
- 27. Pharmacokinetics and pharmacodynamics of intravesical mitomycin C for bladder cancer. OSUCCC/Italian Joint Symposium, May, 1991 (symposium speaker).
- 28. Pharmacodynamics of mitomycin C in cultured human bladder cancer. AAPS Symposium, November, 1991 (symposium speaker).

- 29. Pharmacokinetics and pharmacodynamics of intravesical therapy for bladder cancer. Faculty of Pharmacy, University of Toronto, Canada, November, 1991.
- 30. Pharmacokinetic and pharmacodynamic approaches to improve therapeutic efficacy intravesical mitomycin C in bladder cancer as an example. College of Pharmacy, University of Houston, December, 1991.
- 31. Regional intravesical mitomycin C of bladder cancer- pharmacologic studies to clinical trials. College of Pharmacy, University of Tennessee, February, 1992.
- 32. Regional intravesical mitomycin C of bladder cancer-pharmacologic studies to clinical trials. School of Pharmacy, University of California San Francisco, March, 1992.
- Regional intravesical mitomycin C of bladder cancer- pharmacologic studies to clinical trials. Department of Experimental Therapeutics and Grace Cancer Drug Center, Roswell Park Memorial Institute, May 1992.
- 34. Use of explant culture for pharmacodynamic studies. Spring meeting of the Ohio Valley Branch of the Tissue Culture Society, June, 1992.
- 35. Design of optimized intravesical mitomycin C treatment for superficial bladder cancer. University of Antwerp, August, 1992.
- 36. Pharmacologic studies to optimize intravesical mitomycin C treatment for superficial bladder cancer. Department of Physiology, The Ohio State University, November, 1992.
- 37. Pharmacokinetic and pharmacodynamic approaches to optimize cancer treatment regimens. Frank Duckworth Eminent Visiting Scholars Seminar Series, College of Pharmacy, University of Florida, September, 1993.
- 38. Pharmacokinetic and pharmacodynamic approaches to optimize cancer treatment regimens. University of Pittsburgh, December, 1993.
- 39. Pharmacokinetic and pharmacodynamic approaches to optimize cancer treatment regimens. Department of Hematology/Oncology, College of Pharmacy, Case Western Reserve University, February, 1994.
- 40. Pharmacokinetic and pharmacodynamic studies to improve cancer chemotherapy. University of California at San Francisco, Department of Pharmaceutical Chemistry, May, 1994.
- 41. Cancer Diagnostics and Therapeutics: Research Perspective. Bio Tech Ohio '94, Columbus, OH, June, 1994 (symposium speaker).
- 42. Molecular pharmacodynamics of anticancer drugs. Seventh Japanese-American Conference on Pharmacokinetics and Biopharmaceutics, Hiroshima, Japan, August, 1994 (symposium speaker).

- 43. Pharmacologic basis for intravesical therapy. 16th Annual Meeting of the Ohio Valley-Lake Erie Association of Cancer Centers conference. Pittsburgh Cancer Institute, University of Pittsburgh, and the Ohio Valley-Lake Erie Association of Cancer Centers, October, 1994 (symposium speaker).
- 44. Pharmaceutical sciences in the 90's and beyond An academic perspective. AAPS Career Issues Forum, Am. Assoc. Pharmaceut. Scientists Annual Meeting, San Diego, CA, November, 1994 (symposium speaker).
- 45. Pharmacokinetic and pharmacodynamic studies to improve cancer chemotherapy. University of Michigan, Ann Arbor, MI, November, 1994.
- 46. Pharmacokinetic and pharmacodynamic studies to improve cancer chemotherapy. Purdue University, West Lafayette, IN, April, 1995.
- 47. Translation of laboratory findings to clinical applications: Intravesical chemotherapy as an example. Emory University, Atlanta, GA, June, 1995.
- 48. Pharmacodynamics and therapy development. Grand Rounds, The Ohio State University Hospitals and Arthur G. James Cancer Hospital and Research Institute, Columbus, OH, March, 1996.
- 49. Pharmacodynamics in cancer treatment. University of Nebraska Medical Center, Omaha, NE, April, 1996.
- 50. Application of pharmacokinetics and pharmacodynamics to improve cancer patient treatment. Joseph V. Swintosky Distinguished Lecture Series. University of Kentucky, College of Pharmacy, Lexington, KY, April, 1997.
- 51. Application of pharmacodynamic analysis to optimize cancer chemotherapy. American Association of Pharmaceutical Scientists Midwest Regional Meeting, Chicago, IL, May, 1997 (symposium speaker).
- 52. Site-dependent pharmacodynamics of anticancer drugs. 4th International Workshop on the Pharmacodynamics of Anticancer Agents. Pershire, Scotland. August, 1998 (symposium speaker).
- 53. Pharmaceutics and Pharmacodynamics of Intracellular Signaling Events, Pharmaceutics/Pharmaceutical Sciences Department Chair Meeting, 1999 Annual AAPS Meeting, New Orleans, November, 1999.
- 54. Successful translational research: Intravesical chemotherapy, Grand Rounds, The Ohio State University Hospitals and Arthur G. James Cancer Hospital and Research Institute, Columbus, OH, January, 2000.
- 55. Fibroblast growth factors: A new epigenetic mechanism of anticancer drug resistance. CTEP, NCI, NIH, March, 2000.

- 56. Pharmacology of paclitaxel. Guilford Pharmaceuticals, Baltimore, MD, March, 2000.
- 57. Pharmacokinetics- and pharmacodynamics-directed clinical trial design. ILEX, San Antonio, TX. June, 2000.
- 58. Mechanisms of chemoresistance in non-small cell lung cancer How might we overcome them. State of the science meeting, CTEP, NCI, Washington, DC, June, 2000.
- 59. Pharmacokinetics/pharmacodynamics-directed therapy development A model for successful translational research. Ground Rounds, Eppley Cancer Center, Omaha, NE. July, 2000.
- 60. Pharmacologically optimized intravesical chemotherapy: Results of a phase III trial. State of the science workshop on superficial bladder cancer. Washington, DC, September, 2000.
- 61. Fibroblast growth factors and chemoresistance. State of the science workshop on superficial bladder cancer. Washington, DC, September, 2000.
- 62. Role of pharmacogenomics in the pharmacy profession. Ohio Pharmaceutical Seminar, September, 2000.
- 63. Pharmacokinetics/pharmacodynamics-directed cancer chemotherapy development: A model for successful translational research. University of Illinois at Chicago, September, 2000.
- 64. Determinants of drug delivery to solid tumors. NCI/Controlled Release Society International Symposium on "Targeted drug delivery to tumors", Washington, D.C., September, 2000.
- 66. Pharmacokinetics/pharmacodynamics-directed cancer chemotherapy development: A model for successful translational research. National University of Singapore, October, 2000.
- 67. Fibroblast growth factors: A new epigenetic mechanism of broad spectrum resistance to anticancer drugs. National University of Singapore, October, 2000.
- 68. Fibroblast growth factors: A new epigenetic mechanism of broad spectrum resistance to anticancer drugs. National Health Research Institutes, Taipei, Taiwan, October, 2000.
- 69. Pharmacokinetics/pharmacodynamics-directed cancer chemotherapy development: A model for successful translational research. National Defense Medical University, Taipei, Taiwan, October, 2000.
- 70. Pharmacokinetics/pharmacodynamics-directed cancer chemotherapy development: A model for successful translational research. National Taiwan University, Taipei, Taiwan, October, 2000.
- 71. Fibroblast growth factors: A new epigenetic mechanism of broad spectrum resistance to anticancer drugs. Catholic Medical University, Seoul, Korea, October, 2000.
- 72. Pharmacokinetics/pharmacodynamics-directed cancer chemotherapy development: A model for successful translational research. Seoul National University, Seoul, Korea, October, 2000.
- 73. Determinants of drug delivery to solid tumors. NCI/Controlled Release Society International

Symposium on "Targeted drug delivery to tumors", Washington, D.C., September, 2000.

- 74. Pharmacokinetics- and pharamcodynamics-directed clinical trial design. Supergen, November, 2000.
- 75. Biological manipulation to enhance drug delivery to tumors. Tenth International Symposium on Recent Advances in Drug Delivery Systems, February, 2001.
- 76. Application of mathematical modeling to design of cancer chemotherapy. Department of Chemical Engineering, OSU, February, 2001.
- 77. Pharmacologically optimized intravesical chemotherapy: Results of a phase III trial. International Bladder Symposium, Washington, DC, March, 2001.
- 78. Application of mathematical modeling to design of cancer chemotherapy. Department of Applied Mathematics, OSU, April, 2001.
- 79. FGF-induced drug resistance: From mechanism to bedside. Cleveland Clinic Foundation, June, 2001.
- Low-Dose Suramin Plus Paclitaxel/Carboplatin-Preclinical Rationale. National Cancer Institute, CTEP Drug Development, Fall 2001 Phase I Meeting, Bethesda, MD, September, 2001.
- 81. Enhancement of delivery of drugs and nanoparticles through biological manipulations. Biomems & Biomedical Nanotechnology Conference, Columbus, OH, Sept., 2001.
- 82. Determinants of drug transport and delivery. The Foundation Fighting Blindness, San Francisco, CA., October, 2001.
- 83. Determinants and barriers for drug transport in solid tumors. AAPS Annual Meeting and Exposition, Denver, CO., October, 2001.
- 84. Co-Chair, Technical Session: Health & Medicine, 2002 OCAPA Annual Symposium, Columbus, OH., June, 2002.
- 85. Department of Pharmacology, College of Medicine and Public Health, Ohio State University, Translational Cancer Therapeutics, August, 2002.
- 86. Approaches to improve cancer chemotherapy efficacy. Alza Corporation, Palo Alto, CA., December, 2002.
- 87. Cancer therapy development. Vanderbilt University, Nashville, TN, September, 2003.
- 88. Cancer therapy development. Roswell Park Cancer Institute, Buffalo, NY, October, 2003.
- 89. Multi-disciplinary approaches to cancer therapy development. University of Michigan, Ann Arbor, MI, November, 2003.

- 90. Cancer therapy development: A tale of two paradigm shifts. Pfizer, Ann Arbor, MI, November, 2003.
- 91. Methods to improve efficacy of intravesical chemotherapy. International Conference on intravesical therapy. Padua, Italy, November, 2003.
- 92. Application of computational modeling to clinical trial design. Mathematical Bioscience institute. Ohio State University, November, 2003.
- Integration of pharmacokinetics and pharmacodynamics for effective cancer therapy development: A tale of two paradigm shifts. Bristol-Myers Squibb, Princeton, NJ, December, 2003.
- 94. Multi-disciplinary approaches to cancer therapy development: A tale of two paradigm shifts. University of Utah. Salt Lake City, UT, March, 2004.
- 95. Cancer therapy development. Biomedicines, Inc. Emerysville, CA. May, 2004.
- 96. Fibroblast growth factor inhibitors: From laboratory to bedside. Plenary lecture. Second Pharmaceutical Sciences World Congress, Kyoto, Japan. June, 2004.
- 97. Cancer therapy development: A tale of two paradigm shifts. Case Western Reserve University. July, 2004.
- 98. Tumor penetrating particles for intraperitoneal cancer treatment. NexMed Inc., Robinsville, NJ. July, 2004.
- 99. Development of bladder cancer intravesical chemotherapy. Eli Lilly Inc., Indianapolis, IN. August, 2004.
- 100. Cancer therapy development: A tale of two paradigm shifts. Cleveland Clinic Foundation, August 2004.
- 101. Rational cancer therapy development: theory and practice. Enzon Inc., September 2004.
- 102. Cancer therapy development: A tale of two paradigm shifts. University of Minnesota, September, 2004.
- 103. Rational cancer therapy development: theory and practice. Roswell Park Cancer Institute, September, 2004.
- 104. Paclitaxel pharmacology. Boston Scientific Co., Minneapolis, MN. September, 2004.
- 105. Paclitaxel pharmacology. Boston Scientific Co., Natick, MA. October, 2004.
- 106. Cancer therapy development: A tale of two paradigm shifts. Vermont Cancer Center regional research symposium. Burlington, VT. October, 2004.

- 107. Shifting paradigms in cancer therapy development. Center for Drug Evaluation and Research. U.S. Food and Drug Administration. MD, November, 2004.
- 108. Paradigm Shifts in Cancer Therapy Development: PD-based approaches. PPDM Research Achievement Award Lecture. Baltimore, MD, November 2004.
- 109. Shifting paradigms in cancer therapy development. Office of Clinical Pharmacology & Biopharmaceutics. U.S. Food and Drug Administration. MD, January 2005 (Visiting Professor Program).
- Computational modeling of paclitaxel pharmacology. Office of Clinical Pharmacology & Biopharmaceutics. U.S. Food and Drug Administration. MD, January 2005 (Visiting Professor Program).
- 111. Paradigm Shifts in Cancer Therapy Development. University of Texas MD Anderson Cancer Institute, January 2005.
- 112. Paradigm Shifts in Cancer Therapy Development. University of Southern California, Los Angeles, January 2005.
- 113. Interdisciplinary approach to cancer drug development. Pharmacology Day at University of Buffalo & Roswell Park Cancer Institute, May 2005.
- 114. Translational sciences: A new frontier for pharmaceutical scientists. Graduate Student Symposium. University of Toronto, July 2005.
- 115. Pharmaceutical and translational sciences: A multi-disciplinary platform for cancer therapy development. University of Utah, September 2005.
- 116. Translational sciences: A multi-disciplinary platform for cancer therapy development. Keynote speaker. University of Davis Cancer Center Symposium, October 2005.
- 117. Paradigm Shifts in Cancer Therapy Development: PD-based approaches. Korean Society of Pharmaceutics.Pharmaceutical Sciences and Technology. Seoul, Korea. December 2005.
- 118. PK/PD: Importance in Cancer Therapy Development & Translational Sciences. Hong Kong Chinese University, Hong Kong. December 2005.
- 119. Translational sciences: A multi-disciplinary platform for cancer therapy development. National Health Research Institute, Taiwan. December 2005.
- 120. Translational sciences: A multi-disciplinary platform for cancer therapy development. Nektar Inc., South San Francisco, January, 2006.
- 121. Pharmacology-based therapy development: A model for interdisciplinary translational research. University of California, Davis. March 2006.

122. Molecular targets and biomarkers in cancer chemotherapy. Third International Pharmaceutical Sciences World Congress, Amsterdam. April 2007.

RESEARCH SUPPORT

A. Summary of past and current grants.

Current Support							
Direct Cost				Total of Direct & Indirect Costs*			
Role	NIH	Other Agencies	Total				
P.I.	\$6,550,046	-0-	\$6,550,046	\$			
Co-P.I.	\$1,618,990	-0-	\$1,618,990	\$			
Co-I.	\$31,623,296	\$	\$	\$			
Subtotal	\$39,792,332	\$	\$	\$			
Combined 3	Combined Past and Current Support						
P.I.	\$10,713,415	\$	\$	\$			
Co-P.I.	\$9,918,755	\$	\$	\$			
Co-I.	\$54,969,177	\$	\$	\$			
Total	\$75,601,347	\$	\$	\$			
Pending su	Pending support						
P.I.	\$	0	\$	\$			
Co-P.I.	\$0	0	\$0	\$0			
Co-I.	\$	0	\$	\$			
Total	\$	0	\$	\$			

*Estimated using 47.5% IDC (current rate is 49.5%). Included the parent grants.

B. <u>Listing of Research Grants.</u> The following lists only the direct cost amount.

B1. Current Support

- 1. (P.I.) Suramin to enhance efficacy of paclitaxel and carboplatin. National Cancer Institute, NIH, 1R21 CA91547, 9/19/01-8/31/05, total direct cost \$450,000. Currently on no-cost extension.
- (P.I.) Pharmacodynamics of agents for bladder cancer intravesical therapy. National Cancer Institute, NIH, R37 CA49816 (MERIT Award), 6/89-5/05, total direct cost \$3,616,831. Renewal application planned for 7/1/06.
- 3. (P.I.) Chemoresistance in renal cell cancer. R01 CA93871 & R01 CA93871-01S1. National Cancer Institute, NIH, 08/02-7/07, annual direct cost, \$225,000; total direct cost, \$1,175,000.

- 4. (P.I.) FGF: A mechanism of acquired multi drug resistance. R01CA97067. National Cancer Institute, NIH, 07/02-6/06, annual direct cost \$166,250; total direct cost, \$665,000.
- 5. (P.I.) Telomeres, telomerase and chemotherapy. National Cancer Institute, NIH, R01 CA77091, 7/98-6/05, total direct cost \$643,215. Renewal application submitted on 7/05 (see below).
- 6. (Co-PI) Chemoresistance in pancreatic cancer (P.I., Guill Wientjes). R01CA100922. National Cancer Institute, NIH, 3/04-2/09, annual direct cost, \$184,500; total direct cost, \$992,500.
- (Co-P.I.) A Phase I/II Study of Suramin in Combination with Paclitaxel in Advanced (Stage IIIB or IV) Metastatic Breast Cancer" (P.I., Charles Shapiro). NCI for the Avon Foundation -NCI Progress for Patients Awards Program, 6/04-5/06. Total direct Costs \$351,490.
- (Co-P.I.) Tumor priming to promote nanoparticle gene delivery (P.I., M. Guill Wientjes). R21CA111770. National Cancer Institute, NIH. 7/05-9/07. Annual direct costs, \$150,000. Total direct costs, \$275,000.
- (Co-I./Consultant) Apoptosis Induction to Enhance Tumor Targeting (P.I., Ze Lu, Ph.D.). National Cancer institute, FLAIR, R43CA103133, 8/01/03 – 7/31/05, total direct costs \$412,597.
- (Co-I./Consultant) Bladder tumor targeting by intravesical paclitaxel (P.I., Teng-Kuang Yeh). National Cancer Institute, FLAIR, R43CA107743, NIH, 6/04-5/06, annual direct cost, \$225,000; total direct cost, \$450,000.
- (Co-I./Consultant) Broad-spectrum protection against chemotherapy-induced alopecia (P.I., Ze Lu). R43CA110706. National Cancer Institute, NIH, 9/05-8/06, annual direct cost, \$150,000.
- 12. (Co-I.) Post-amputation adjuvant suramin and doxorubicin in dogs with osteosarcoma (P.I.,
 Morris Animal Foundation. 9/05-10/07. Annual direct cost, \$
 Total direct costs, \$
- 13. (Co-I.) OSU Comprehensive Cancer Center Core Grant (P.I., Michael Caligiuri): National Cancer Institute, NIH, P30 CA16058, 7/04-6/09, total direct cost, \$22,947,064.
- 14. (Faculty Mentor) Oncology Training Grant (P.I., Michael Caligiuri). T32CA09338. National Cancer Institute, NIH; total direct costs, \$2,049,526.
- 15. (Co-I.) Phase I evaluation of anticancer drugs. (P.I., Michael Grever). National Cancer Institute, NIH. U01CA76576, 2/03-1/08, \$3,504,379 total direct cost.
- 16. (Co-I.) Mathematical Bioscience Institute (P.I., Avner Friedman). National Science Foundation, 7/02-6/07, total direct costs, \$10,000,000.
- 17. (Co.-I.) Center for Grid-Enabled Medical Image Analysis (P.I., Joel Saltz). P20CB000591. National Cancer Institute, NIH, 07/01/03-06/30/06, direct costs \$2,109,730.

B.2. Pending Support



B.3. <u>Past Support</u>

- (P.I.) Pilot studies on tissue selectivity of 5-fluorouracil prodrugs. Roswell Park Memorial Institute (RPMI) Basic Research Support Grant, NIH, RR-05648, 12/80-11/81, total direct cost \$4,750.
- 2. (P.I.) Pilot studies on tissue selectivity of 5-fluorouracil prodrugs. Private donation to RPMI, 8/80-3/81, total direct cost \$
- 3. (P.I.) Tissue selectivity of 5-fluorouracil prodrugs. National Cancer Institute, NIH, RO1 CA31474, 2/82-7/83, \$43,800.
- 4. (P.I.) Tissue selectivity of 5-fluorouracil prodrugs. National Cancer Institute, NIH, RO1 CA37110, 8/83-8/86, \$58,374.
- 5. (P.I.) Mechanism and selective modulation of gastrointestinal toxicity of 5-fluorouracil. OSU Seed Monies Grants, 11/84-7/86, \$
- 6. (P.I.) Selective reduction of gastrointestinal toxicity of 10/85-9/86, \$
- 7. (P.I.) Intravesical chemotherapy of bladder cancer. Elsa Pardee Foundation 1/87-12/87,

- 8. (P.I.) In vitro test of intestinal toxicity of antineoplastics. National Cancer Institute, NIH, R43 CA44227, 6/87-11/87, \$45,568.
- 9. (P.I.) Yamagiwa-Yoshida Fellowship for Dr. 1987, State of the second second
- 10. (P.I.) Intestinal toxicity of 5-fluorouracil and leucovorin. National Cancer Institute, NIH, RO1 CA43365, 5/87-4/91, total direct cost \$175,339.
- 11. (P.I.) Pharmacology of dideoxynucleosides in small intestine. National Institute of Allergy and Infectious Diseases, NIH, R01 AI29133, 9/89-7/92, total direct costs \$213,338.
- 12. (P.I.) Research Career Development Award, K04 CA01497, National Cancer Institute, NIH, 9/90-8/95, \$300,389.
- 13. (P.I.) Exchange Scholar Fellowship protection, Ph.D.) Apoptosis and differentiation in prostate cancer cells. Fondation pour la Recherche Medical, 4/95-9/95 and 3/96-8/96, \$ total direct costs, and Societé Française du Cancer 10/95-12/95, \$ total direct costs.
- 14. (P.I.) Institutional Research Grant to Ohio State University. American Cancer Society, IRG-16-34, 7/95-6/97, total annual cost \$ total cost \$
- 15. (P.I.) Pharmacodynamics of taxol in human solid tumors. National Cancer Institute, NIH, R01 CA63363, 4/94-3/98, annual direct cost \$179,502, total direct cost \$690,228.
- 16. (P.I.) Studies on anticancer drugs. \$ 1993-2001,
- 17. (P.I.) clinical trial in superficial bladder cancer patients. 1993-2000. \$ gift in kind (drug supplies).
- 18. (P.I.) Analysis of anticancer drugs. \$ 1997-2000. Battelle Memorial Institute.
- 19. (P.I.) Chemoresistance in metastatic tumors. National Cancer Institute, NIH, R01CA78577, 9/98-8/03, total direct cost \$626,671.
- 20. (P.I. and Project Coordinator) Determinants of mitomycin C sensitivity in human tumors. National Cancer Institute, NIH, R01 CA58988, 5/93-4/03, total direct cost \$791,608.
- 21. (Co.-P.I. and Project Coordinator) Target site pharmacokinetics of mitomycin C in bladder cancer patients (P.I., Guill Wientjes). National Cancer Institute, NIH, R01 CA58983, 5/93-4/01, total direct cost \$456,211.
- 22. (P.I. and Project Coordinator) Pharmacology based efficacy trial of intravesical mitomycin C. National Cancer Institute, NIH, R01 CA58989, 5/93-4/03, total direct cost \$757,093. Grants #20, 21 & 22 are interactive research projects (one of the funding mechanisms of the National Cancer Institute). I was the Project Coordinator of these grants (analogous to the P.I. of a program grant).

- 23. (Co-P.I.) Delivery of anti-AIDS drug 2',3'-dideoxyinosine (P.I., Guill Wientjes). National Institute of Allergy and Infectious Diseases, NIH, R01 AI28757, 9/89-8/92, total direct cost \$246,906.
- 24. (Co.-P.I.) Novel agents for prostate cancer (P.I., Cancer of the Prostate, 11/95-10/96, total direct cost, \$
- 25. (Co.-P.I.) Regional Lymph node targeting for cancer chemotherapy (P.I., Content of the Conte
- 26. (Co-P.I.) OSU Comprehensive Cancer Center Core Grant (P.I., David Schuller): Deputy Director and Co-Director of Urology Oncology Program. National Cancer Institute, NIH, P30 CA16058, 7/95-6/99, annual direct cost \$1,350,057, total direct cost \$5,786,539.
- 27. (Co-P.I.) Program development grant on breast cancer (P.I., R.W. Brueggemeier, Ph.D.). National Cancer Institute, NIH, P20 CA66193, 9/94-9/98, annual direct cost \$283,425 (my portion is \$35,055), total direct cost \$1,086,901.
- 28. (Co-P.I.) OSU Comprehensive Cancer Center Program Project Development Grant (P.I. 7/1/97-6/30/99, annual direct cost \$ total direct cost.
- 29. (Co-P.I.) Intraprostatic doxorubicin therapy (P.I. Guill Wientjes). National Cancer Institute, NIH, R01CA74179, 8/97-7/02, total direct cost \$1,179,419.
- 30. (Co-I.) Oncology Training Grant (P.I., Stanley Balcerzak). National Cancer Institute, NIH, T32 CA09338-17, 7/94-6/00, annual direct cost \$179,552, \$1,464,896 total direct cost.
- 31. (Co-I.) Tissue selectivity of 5-fluorouracil prodrugs (P.I., Gerald Murphy). Parent grant: RPMI Core Center Grant, Developmental funds, National Cancer Institute, NIH, PO1 CA16056-07, 7/81-6/82, \$21,854, total amount of the entire parent grant was \$439,839.
- 32. (Co-I.) Clinical pharmacology of antineoplastics (P.I., Patrick Creaven). Parent grant: Clinical pharmacology program grant, National Cancer Institute, NIH, PO1 CA21071, 9/79-7/83, \$165,000, total amount of the entire parent grant was \$2,259,929.
- (Co-I.) Pharmacological studies of antineoplastic agents (P.I., David Yohn). Parent grant: OSU Core center grant, Developmental Funds, National Cancer Institute, NIH, P3OCA16058-12, 7/83-6/86, \$88,000, total amount of the entire parent grant was \$3,984,522.
- 34. (Co-I.) Phase II evaluation of anticancer drugs. (P.I., Stanley Balcerzak & Eric Kraut). National Cancer Institute, NIH. 11/98-10/01, \$1,380,900 total direct cost.
- 35. (Co-I.) Phase I Trials of Anti-Cancer Agents (P.I., Stanley Balcerzak & Mike Grever). National Cancer Institute, NIH, 02/01/03-01/31/08, annual direct costs \$519,681, estimated total direct costs, \$2,598,405.

- (Co-I.) Regulation of PTHrP in squamous cell carcinoma by TGFb. (P.I. Thomas Rosol). National Institute of Arthritis and Multiple Sclerosis, NIH, R01AR40220, 4/98-6/03, total direct cost \$825,073.
- 37. (Co-I.) OSU Comprehensive Cancer Center Core Grant (P.I., Clara Bloomfield): National Cancer Institute, NIH, P30 CA16058, 7/99-6/04, total direct cost \$8,683,241.
- 38. (Co-I.) Oncology Training Grant (P.I., Michael Caligiuri). National Cancer Institute, NIH, T32 CA09338-17, 7/99-6/04, total direct costs, \$1,709,076.

RESEARCH INSTRUCTION

A. <u>Major dissertation advisor to graduate students (Predoctoral training)</u>



B. <u>Dissertation co-advisor to graduate students (Predoctoral training)</u>





C. <u>Post-doctoral and post-graduate fellows</u>



D. <u>Visiting Scientists and Faculty</u>



E. <u>Undergraduate students</u>





F. <u>Medical Students</u>



G. <u>Minority Students</u> (NIH Research Apprentice Summer Program for H.S. students)



H. <u>Member of dissertation committee to Ph.D. students</u>





I. <u>Student Awards</u>

<u>Name</u>	Award	<u>Year</u>