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CAREER THEME

Applied Pharmacology and Drug Development/Regulation:
Relationships among concepts, experiments *in vitro*, animal models, and clinical trials

ACADEMIC BACKGROUND

Lecturer in Medicine, Johns Hopkins University, 1983-2005

Associate Professor of Pharmacology, Georgetown University, 1989-2005

Adjunct Faculty, Division of Clinical Pharmacology and Medical Toxicology,
Uniformed Services University of the Health Sciences, 1988-present

Consultant in Research, George Washington University, Department of Pharmacology, 1984-93

Postdoctoral Fellow in Clinical Pharmacology, Johns Hopkins University, 1976 to 1979

Ph.D., Chemical and Biochemical Engineering, University of Pennsylvania, 1976; M.S., l974
Ford Foundation Fellow, University of Pennsylvania, l972-73

B.S. (with honors), Chemical Engineering, Drexel University, 1972.
President, Debate Society. Vice-President, Student Government

Food and Drug Administration

2008-2012 Member, Pharmaceutical Sciences Advisory Committee
2005-2010 Guest Researcher, Laboratory of Clinical Pharmacology, CDER, FDA
2004-2005: Co-Chair, Novel Imaging Probes Subcommittee, NCI-FDA Oncology Task Force
2004-2005: Co-Chair, FDA-Wide Working Group on Imaging in Drug Development
2003-2005: Acting Director, Division of Applied Pharmacology Research, CDER, FDA
1990-2005: Director, Laboratory of Clinical Pharmacology, CDER, FDA
1990-1995: Director, Office of Research Resources, CDER, FDA
1988-1990 Pharmacologist, Office of Research Resources, Center for Drug Evaluation and Research

National Institutes of Health

2005-present Associate Director for Developmental Therapeutics, Division of Cancer Treatment and Diagnosis, NCI, NIH
1983-1988: Chief, Pharmacokinetics Section, Clinical Pharmacology Branch, NCI
1982-1988: Chair, Blood Level Working Group, NCI
1977-1983: Senior Staff, Biomedical Engineering and Instrumentation Branch, Office of Research Services, NIH
1977-1979: Guest Researcher, Laboratory of Toxicology, Developmental Therapeutics, NCI

Publications: Author or co-author of more than 200 articles and 9 patents issued

Employment History **Jerry M. Collins**

2005-present: Associate Director for Developmental Therapeutics,
Division of Cancer Treatment and Diagnosis, NCI, NIH

Supervisor for the Developmental Therapeutics Program at the National Cancer Institute.
Line manager for preclinical drug development activities, with full responsibility for budget, space, and personnel. Program includes 70 Federal employees and about 200 contractors.
As part of the senior management team for the Division, I coordinate preclinical activities with other Programs to facilitate entry of new drugs into clinical testing, as well as the integration of emerging technologies such as noninvasive imaging into clinical therapeutics.

1988-2005: Director, Laboratory of Clinical Pharmacology, CDER, FDA

After a pilot and planning phase with recruitment and equipping a new facility, this lab was formally launched in 1990. The staff in this lab conduct research encompassing laboratory experiments and collaborative clinical studies in the areas of drug metabolism, drug-drug interactions, hepatotoxicity, and positron emission tomography (PET). Over a 15-year period, the size of this group has ranged from 6 to 20 scientists. Lab staff, including myself, also serve as consultants to FDA review operations. My review and policy activities have focused upon the interface between preclinical and clinical trials.

2003-2005: Acting Director, Division of Applied Pharmacology Research, CDER, FDA

The preclinical teams emphasize pharmacogenomics and molecular toxicology, as well as animal studies in vivo that focus upon the cardiopulmonary system, including the effects of anthracyclines on the heart. While continuing my duties as Director of the Laboratory of Clinical Pharmacology, I have full responsibility for allocation of budget, space, and personnel for both groups.

1990-95: Director, Office of Research Resources, CDER, FDA, Senior Executive Service

I managed a diverse group of 212 federal employees, including reviewers of NDA/IND submissions, preclinical and clinical researchers, and drug quality testers. I had full budget, space, and personnel authority for:

-- Division of Biopharmaceutics: reviewed all human pharmacokinetic data related to new drugs. This group traditionally focused upon drug applications in the final stage before marketing (NDAs), but I increased their involvement in evaluation of drugs at earlier stages of investigation (INDs). Division staff analyze of cross-study trends [such as effects of age, gender, organ function] using advanced bio-statistical methods.

-- Division of Research and Testing: included laboratory programs for analytical methods validation for antibiotics and hormones and the certification of insulin. This Division also conducted research into the pharmacology and toxicology of drugs across the entire spectrum of the mission of CDER. Our emphasis was particularly geared towards the replacement of animal testing in vivo with testing in vitro or via chemical-physical methods.

-- Division of Drug Analysis: tested finished drug products and bulk drug substances for adherence to compendial and ANDA/NDA specifications. This group also developed and evaluated technology related to methods for drug testing.

-- Clinical Pharmacology: While serving as ORR Director, I also continued to direct the Clinical Pharmacology Lab <described above>, which was part of ORR.

Additional Duties:
FDA Commissioner's CRADA Review Board. Member, 1994-2005.
SBRS Credentialing Committee. Member, 1995-2005.
Drug Metabolism/Drug Interaction Working Group. Chair and Member, 1994-2005.
FDA Pharmacogenomics Working Group. Member, 2002-2005.
FDA Cross-Center Imaging Initiative. Co-Chair, 2003-2005.
NCI-FDA Inter-Agency Oncology Task Force. Co-Chair, Novel Imaging Probes Subcommittee, 2004-2005.
Institutional Official for CDER's radioactivity license, Nuclear Regulatory Commission, 1990-2005

Other Assignments:
Institutional Official for oversight of CDER's Animal Care and Use Committee (IACUC)
Supervisor for the operations of the CDER Laboratory Scientist Peer Review Committee.
Supervisor for laboratory safety issues at CDER
CDER Liaison, National Center for Toxicology Research

1983-1988: Chief, Pharmacokinetics Section, Clinical Pharmacology Branch, NCI, NIH

I was recruited as the founding director for this group. Our mission was to conduct research on the pharmacokinetics of anticancer drugs, especially those under investigation at the NIH Clinical Center. Specific areas of interest included regional drug delivery, re-evaluation of established agents, and improvements in the testing of new drugs. Collaborative projects included other groups at NCI, other Federal Agencies, and universities.

Additional Duty: Member, Decision Network Committee, DCT/NCI, 1984-88.

1982-1988: Chair, Blood Level Working Group, NCI, NIH

Evaluation of pharmacologically-guided phase 1 clinical trials as an alternative to modified Fibonacci design. Worked with NCI staff in DTP to modify Pharmacology Task Order contracts to provide essential preclinical data for comparison with initial human pharmacology. Served as co-investigator on NCI-CTEP-supported clinical studies that implemented new phase 1 designs.

1977-1983: Staff, Biomedical Engineering and Instrumentation Branch,
Office of Research Services, NIH
Initially, I served in this position via the Intergovernmental Personnel Act (IPA) while maintaining my appointment at Johns Hopkins University. I was appointed to a full-time federal position in 1979. Most of my research activities focused upon the application of pharmacokinetics to the design and analysis of clinical trials of anticancer drugs.

1977-1979: Guest Researcher, Laboratory of Toxicology, Developmental Therapeutics Program (DTP), NCI, NIH.
Conducted independent laboratory research on the pharmacokinetics and toxicity of the drugs under consideration for clinical use via intraperitoneal therapy.

Jerry M. Collins - - - Publications List

(1) J. M. Collins, D. A. Blake, P. G. Egner. Phenytoin metabolism in the rat: Pharmacokinetic correlation between in vitro hepatic microsomal enzyme activity and in vivo elimination kinetics. Drug Metab Disp 6:251-257, 1978

(2) D. A. Blake, J. M. Collins, B. C. Miyasaki, F. Cohen. Influence of pregnancy and folic acid on phenytoin metabolism by rat liver microsomes. Drug Metab. Disp. 6:246-250, 1978.

(3) J. M. Collins. Isobaric inert gas supersaturation: observations, theory, and predictions. J Appl Physiol 44:914-917, 1978.

(4) J. M. Collins. Peritoneal dialysis for methyprylon intoxication. J. Pediatrics 92:519, 1978. (Letter)

(5) B. I. Sikic, J. M. Collins, E. G. Mimnaugh, T. E. Gram. Improved therapeutic index of bleomycin when administered by continuous infusion in mice. Cancer Treat. Rep. 62:2011-2017, 1978.

(6) J. L. Speyer, J. M. Collins, R. L. Dedrick, M. F. Brennan, A. R. Buckpitt, H. Londer, V. T. DeVita, C. E. Myers. Phase I and pharmacological studies of intraperitoneal 5-fluorouracil. Cancer Res. 40:567-572, 1980.

(7) J.M. Collins, R.L. Dedrick, F.G. King, J.L. Speyer, C.E. Myers. Nonlinear pharmacokinetic models for 5-fluorouracil in man: Intravenous and intraperitoneal routes. Clin. Pharmacol. Ther. 28:235-246, 1980.

(8) R.B. Jones, J.M. Collins, C.E. Myers, A.E. Brooks, S.M. Hubbard, J.E. Balow, M.F. Brennan, R.L. Dedrick, V.T. DeVita. High-volume intraperitoneal chemotherapy with methotrexate in patients with cancer. Cancer Res. 41:55-59, 1981.

(9) J. L. Speyer, P. H. Sugarbaker, J. M. Collins, R. L. Dedrick, R. W. Klecker, C. E. Myers. Portal levels and hepatic clearance of 5-fluorouracil after intraperitoneal administration in man. Cancer Res. 41:1916-1922, 1981.

(10) J.M. Collins. Inert gas exchange rates of subcutaneous and intraperitoneal gas pockets in piglets. Resp. Physiol.46:391-404,1981.

(11) M. E. McManus, A. Monks, J. M. Collins, R. White, J. M. Strong. Nonlinear pharmacokinetics of misonidazole and desmethylmisonidazole in the isolated perfused rat liver. J. Pharmacol. Exp. Ther. 219:669-674, 1981.

(12) C. L. Litterst, J. M. Collins, M. C. Lowe, S. T. Arnold, D. M. Powell, A. M. Guarino. Local and systemic toxicity resulting from large-volume ip administration of doxorubicin in the rat. Cancer Treat. Rep 66:157-161, 1982

(13) J. M. Collins, R. L. Dedrick. Contribution of the lungs to total body clearance: linear and nonlinear effects. J. Pharm. Sci. 71:66-70, 1982.

(14) J. M. Collins, R. L. Dedrick. Pharmacokinetics of Anticancer Drugs, pp. 77-99 in Pharmacologic Principles of Cancer Treatment edited by B. A. Chabner. W.B. Saunders, Philadelphia, 1982.

(15) J. M. Collins, R. L. Dedrick, M. F. Flessner, A. M. Guarino. Concentration-dependent disappearance of fluorouracil from peritoneal fluid in the rat: Experimental observations and distributed modeling. J. Pharm. Sci. 71:735-738, 1982.

(16) N. R. Bachur, J. M. Collins, J. A. Kelley, D. A. Van Echo, R. S. Kaplan, M. Whitacre. Diaziquone, 2,5-diaziridinyl- 3,6-biscarbo ethoxyamino-1,4-benzoquinone, plasma and cerebrospinal fluid kinetics. Clin. Pharmacol. Ther. 31:650-655, 1982.

(17) R. L. Dedrick, M. F. Flessner, J. M. Collins, J. S. Schultz. Is the peritoneum a membrane? ASAIO J. 5:1-8, 1982.

(18) C. E. Myers, J. M. Collins. Pharmacology of intraperitoneal chemotherapy. Cancer Investigation 1:395-407, 1983.

(19) I. G. Kerr, J. Jolivet, J. M. Collins, J. Drake, B. A. Chabner. Test dose for predicting high-dose methotrexate infusions. Clin. Pharmacol. Ther. 33:44-51, 1983.

(20) J.F. Spiegel, M.J. Egorin, J.M. Collins, B.D. Lerner, N.R.Bachur. The murine disposition and pharmacokinetics of the antineoplastic agent, diaziquone (NSC 182986). Drug Metab. Disposit. 11:41-46, 1983.

(21) F. G. King, R. L. Dedrick, J. M. Collins, H. B. Matthews, L.S.Birnbaum. Physiologic model for the pharmacokinetics of 2,3,7,8-tetrachloro-dibenzofuran in several species. Tox. Appl. Pharm. 67:390-400, 1983.

(22) L. Gianni, J. Jenkins, R. Greene, A. S. Lichter, C. E. Myers, J. M. Collins. Pharmacokinetics of the hypoxic radiosensitizers misonidazole and desmethylmisonidazole after intraperitoneal administration in humans. Cancer Res. 43:913-916, 1983.

(23) S. Zimm, J.M. Collins, R. Riccardi, D. O'Neill, P.K. Narang, B.Chabner, D.G. Poplack. Variable bioavailability of oral mercaptopurine: Is maintenance chemotherapy in acute lymphoblastic leukemia being optimally delivered? New Engl. J. Med. 308:1005-1009, 1983.

(24) R.F.Greene, J.M.Collins, J.F.Jenkins, J.L.Speyer, C.E.Myers. Plasma pharmacokinetics of adriamycin and adriamycinol: Implications for the design of in vitro experiments and treatment protocols. Cancer Res. 43:3417-3421, 1983.

(25) J.M.Collins, R.L.Dedrick. Distributed model for drug delivery to the CSF and brain tissue. Amer.J.Physiol.245:R303-R310,1983.

(26) G.A.Curt, J.J.Grygiel, B.J.Corden, R.F.Ozols, R.B.Weiss, D.Tell, C.E.Myers, J.M.Collins. A phase I and pharmacokinetic study of carboplatinum (CBDCA) NSC 241240. Cancer Res.43:4470-4473,1983.

(27) S.Zimm, J.M.Collins, D.O'Neill, B.Chabner, D.G.Poplack. Inhibition of first-pass metabolism in cancer chemotherapy: the interaction of 6-mercaptopurine and allopurinol. Clin. Pharmacol. Ther. 34:810-817, 1983.

(28) G.A.Curt, J.A.Kelley, C.V.Kufta, B.H.Smith, P.L.Kornblith, R.C.Young, J.M.Collins. A Phase II and pharmacokinetic study of aziridinylbenzoquinone (AZQ, diaziquone, NSC 182986) in high grade glioma. Cancer Res. 43:6102-6105, 1983.

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(30) J.M.Collins. Pharmacokinetics of intraventricular administration. J. Neuro-Oncol. 1:283-290, 1983.

(31) R.L.Dedrick, E.H.Oldfield, J.M.Collins. Arterial drug infusion with extracorporeal removal. I. Theoretical basis with particular reference to the brain. Cancer Treat. Rep. 68: 373-380, 1984.

(32) R.F.Ozols, B.J.Corden, J.Collins, R.C.Young. High dose cisplatin in hypertonic saline: Renal effects and pharmacokinetics of a 40 mg/m2 qd x5 schedule, pp. 321-329 in Platinum Coordination Complexes in Cancer Chemotherapy, edited by M.P. Hacker, E.B.Douple, I.H.Krakoff. M.Nijhoff, Boston, 1984.

(33) R.W.Klecker, J.M.Collins. Quantification of tiazofurin in plasma by high-performance liquid chromatography. J.Chrom./Biomed. Appl. 307:361-369, 1984.

(34) T.J.Kinsella, A.Russo, J.B.Mitchell, J.Rowland, J.Jenkins, J.Schwade, C.E.Myers, J.M.Collins, J.Speyer, P.Kornblith, B.Smith, C.Kufta, E.Glatstein. A phase I study of intermittent intravenous bromodeoxyuridine (BUdR) with conventional fractionated irradiation. Int. J. Radiat. Oncol. Biol. Phys. 10:69-76, 1984.

(35) S.Zimm, J.M.Collins, G.A.Curt, D.O'Neill, D.G.Poplack. The cerebrospinal fluid pharmacokinetics of intraventricular and intravenous aziridinylbenzoquinone. Cancer Res.44:1698-1701, 1984.

(36) A.Russo, L.Gianni, T.J.Kinsella, R.W.Klecker, J.Jenkins, J.Rowland, E.Glatstein, J.B.Mitchell, J.Collins, C.Myers. Pharmacological evaluation of intravenous delivery of 5-bromodeoxyuridine to patients with brain tumors. Cancer Res. 44:1702-1705, 1984.

(37) J. M. Collins. Pharmacologic rationale for regional drug delivery. J. Clin. Oncology 2:498-504, 1984.

(38) M. J. Egorin, E. H. Bellis, M. Salcman, J. M. Collins, J. F. Spiegel, N. R. Bachur. The pharmacology of

diaziquone given in intravenous or intracarotid infusion to normal and intracranial tumor-bearing puppies. J. Neurosurg. 60:1005-1013, 1984.

(39) S. Zimm, J. M. Collins, J. Miser, D.C. Chatterji, D. G. Poplack. Cerebrospinal fluid pharmacokinetics of ara-C following intrathecal administration in pediatric patients. Clin. Pharmacol. Ther. 35:826-830, 1984.

(40) J. M. Collins. Therapeutic monitoring of antineoplastic agents. Cancer Bull. 36:191-196, 1984.

(41) I. G. Kerr, S. Zimm, J. M. Collins, D. O'Neill, D. G. Poplack. Effect of intravenous dose and schedule on cerebrospinal fluid pharmacokinetics of 5-fluorouracil in the monkey. Cancer Res. 44:4929-4932, 1984.

(42) J. M. Collins. Pharmacokinetic rationale for intraarterial therapy, In: Intra-Arterial and Intracavitary Cancer Chemotherapy, edited by S.B. Howell. M. Nijhoff, Boston, 1985. Pages 1-10.

(43) J. M. Collins. Pharmacokinetic rationale for intracavitary therapy, In: Intra-Arterial and Intracavitary Cancer Chemotherapy, edited by S.B. Howell. M. Nijhoff, Boston, 1985. Pages 41-51.

(44) B.J.Corden, R. L. Fine, R.F.Ozols, J. M. Collins. Clinical pharmacology of high-dose cisplatin. Cancer Chemother. Pharmacol. 14:38-41, 1985.

(45) J. M. Collins. Pharmacokinetics of 5-fluorouracil infusions in the rat: comparison with man and other species. Cancer Chemother. Pharmacol. 14:108-111, 1985.

(46) S. Zimm, L. Ettinger, J. Holcenberg, B.A.Kamen, T.J.Vietti, J. Belasco, N. Shutta, F. Balis, J.M. Collins, D. G. Poplack. Pediatric phase I and clinical pharmacologic study of mercaptopurine administered as a prolonged intravenous infusion. Cancer Res. 45:1869-1873, 1985.

(47) J.J. Grygiel, F.M. Balis, J.M. Collins, C.M. Lester, D.G. Poplack. Pharmacokinetics of tiazofurin in the plasma and cerebrospinal fluid of rhesus monkeys. Cancer Res. 45:2037-2039, 1985.

(48) R.W. Klecker, J.F. Jenkins, T.J. Kinsella, R.L. Fine, J.M. Strong, J.M. Collins. Clinical pharmacology of 5-iodo-2'-deoxyuridine and iodouracil endogenous pyrimidine modulation.
Clin. Pharmacol. Ther. 38:45-51, 1985.

(49) R. W. Klecker, Jr., and J. M. Collins. Quantification of suramin by reverse-phase ion-pairing high-performance liquid chromatography. J. Liq. Chrom. 8:1685-1696, 1985.

(50) G.A.Curt, J.A.Kelley, R.L.Fine, P.N.Huguenin, J.S.Roth, G.Batist, J.Jenkins, J.M.Collins. A Phase I and pharmacokinetic study of dihydro-5-azacytidine (NSC-264880). Cancer Res. 45:3359-3363, 1985.

(51) J.M.Collins and B.J.Corden. Plasma half-life of cisplatin. Cancer Chemother. Pharmacol. 15:183-184, 1985. (Letter)

(52) J.M.Collins and I.G.Kerr. CSF Pharmacology of 5-fluorouracil. Cancer Res. 45:3399, 1985. (Letter)

(53) J.M.Collins, R.Riccardi, P.Trown, D.O'Neill, D.G.Poplack. Plasma and CSF pharmacokinetics of recombinant leucocyte interferon A in monkeys: Comparison of intravenous, intramuscular, and intraventricular delivery. Cancer Drug Delivery 2:247-253, 1985.

(54) T.J.Kinsella, A.Russo, J.B.Mitchell, J.M.Collins, J.Rowland, D.Wright, E.Glatstein. Phase I study of intravenous iododeoxyuridine as a clinical radiosensitizer. Int. J. Radiat. Oncol. Biol. Phys. 11:1941-1946, 1985.

(55) S.Broder, R.Yarchoan, J.M.Collins, H.C.Lane, P.D.Markham, R.W.Klecker, R.R.Redfield, H.Mitsuya, D.F.Hoth, E.Gelmann, J.E.Groopman, L.Resnick, R.C.Gallo, C.E.Myers, A.S.Fauci. Effects of suramin on HTLV-III/LAV infection presenting as Kaposi's sarcoma or AIDS-related complex: clinical pharmacology and suppression of virus replication in vivo. Lancet ii:627-630, 1985.

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(58) J.M.Collins. Pharmacologic rationale for hepatic arterial therapy. Recent Results in Cancer Research 100:140-147, 1986.

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(60) J.M.Collins, R.W.Klecker, Jr., R.Yarchoan, H.C.Lane, A.S.Fauci, R.R.Redfield, S.Broder, C.E.Myers. Clinical pharmacokinetics of suramin in patients with HTLV-III/LAV infection. J. Clin. Pharmacol. 26:22-26, 1986.

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(62) R.Yarchoan, R.W.Klecker, K.J.Weinhold, et al., J.M.Collins, D.P.Bolognesi, C.E.Myers, S.Broder. Administration of 3'-azido-3'-deoxythymidine, an inhibitor of HTLV-III/LAV replication, to patients with AIDS or AIDS-related complex. Lancet i:575-580, 1986.

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