

**CURRICULUM VITAE**

NAME: Stephen Paul Spielberg

CURRENT POSITION (July, 2003- ):

Professor of Pediatrics, and of Pharmacology and Toxicology  
Dartmouth Medical School  
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Hanover, NH 03755  
Email: [Stephen.P.Spielberg@Dartmouth.edu](mailto:Stephen.P.Spielberg@Dartmouth.edu)

Dean (July, 2003-December, 2007)  
Dartmouth Medical School  
Vice President for Health Affairs  
Dartmouth College

Principal Investigator (2007-)  
Institute for Pediatric Innovation

**EDUCATION:**

A.B.	June, 1966, Princeton University Major: Biology Honors: Graduated Magna Cum Laude Phi Beta Kappa
Ph.D.	December, 1971, University of Chicago, Chicago, Ill. Department: Pharmacology
M.D.	June, 1973, University of Chicago, Chicago, Ill. Honors: Graduated with Honors Alpha Omega Alpha Sigma Xi Graduate training supported by M.D. - Ph.D Training Grant, USPHS HD-00001

POST-GRADUATE TRAINING:

July, 1973 - June, 1975

Intern and Junior Assistant Resident:  
Children's Hospital Medical Center, Boston, Mass.  
Specialty: Pediatrics  
Clinical Fellow in Pediatrics:  
Harvard Medical School

July, 1975 - June, 1977

Clinical Associate in Pediatrics:  
National Institute of Child Health and Human Development, N.I.H.  
Section: Human Biochemical Genetics

PREVIOUS EMPLOYMENT AND FACULTY APPOINTMENTS:

July, 1977 - June, 1978

Instructor:  
Departments of Pediatrics, and Pharmacology and Experimental  
Therapeutics, Division of Clinical Pharmacology, Johns Hopkins  
University School of Medicine

July, 1978 - June, 1981

Assistant Professor:  
Departments of Pediatrics, and Pharmacology and Experimental  
Therapeutics, Division of Clinical Pharmacology, Johns Hopkins  
University School of Medicine  
Active Staff, Pediatrics, Johns Hopkins Hospital

July, 1981 - June, 1989

Associate Professor:  
Departments of Paediatrics and Pharmacology, University of Toronto

July, 1989 - July, 1992

Professor:  
Departments of Paediatrics & Pharmacology, University of Toronto

July, 1981 - June, 1992

Senior Scientist:  
Research Institute, Hospital for Sick Children, Toronto

October, 1986 - March, 1987

Acting Director:  
Division of Clinical Pharmacology, Hospital for Sick Children

March, 1987 - July, 1992

Director:

Division of Clinical Pharmacology and Toxicology, Hospital for Sick Children

July, 1988 - July, 1992

Director:

University of Toronto Centre for Drug Safety Research

July, 1992 - December, 1997

Executive Director, Exploratory Biochemical Toxicology, and Clinical and Regulatory Development, Merck Research Laboratories

January, 1997-June, 2003

Vice President

Pediatric Drug Development

Johnson & Johnson Pharmaceutical Research and Development

January, 1993-June, 2003

Adjunct Professor of Medicine (Clinical Pharmacology) and of Pediatrics

Thomas Jefferson University Medical College

June, 1993-June, 2003

Adjunct Professor of Pediatrics

UMDNJ-Robert Wood Johnson Medical School

#### PROFESSIONAL BOARDS:

Diplomate, National Board of Medical Examiners, July, 1974

Diplomate, American Board of Pediatrics, June, 1979

FRCPC, Medical Scientist, 1987

#### MEDICAL LICENSURE:

State of Maryland, 1975 - 1993.

Ontario College of Physicians and Surgeons, 1981 -1992.

Commonwealth of Pennsylvania, 1992- (Certificate # 048341 L)

State of New Hampshire, 2003- (License # 12119)

#### SELECTED HONORS:

A.B., Magna cum laude, Phi Beta Kappa, Princeton University, 1966.

M.D., With Honors, Alpha Omega Alpha, University of Chicago, 1973.

PMAF Faculty Development Award in Clinical Pharmacology, 1979-1981.  
 Medical Research Council of Canada Scholarship, 1981-1986.

Kenneth M. Piafsky Young Investigator Award, Canadian Society for  
 Clinical Pharmacology, 1984.

Roche Award for best publication of the year, Canadian Society for Clinical  
 Pharmacology, 1986, for Shear, N.H., Spielberg, S.P., et al., *Ann. Intern. Med.* 105,  
 179-184, 1986.

Rawls-Palmer Award and Lectureship, American Society of Clinical Pharmacology  
 and Therapeutics, 1992.

First Recipient, Werner Kalow Award and Lectureship in Pharmacogenetics and Drug  
 Safety, University of Toronto, 1995.

William B. Abrams Lectureship, FDA/ASCPT, 2001.

Award in Excellence in Clinical Pharmacology, PhRMA Foundation, 2007.

Distinguished Service Award, University of Chicago, Pritzker School of Medicine,  
 2008

#### PROFESSIONAL SOCIETIES:

Society for Pediatric Research

American Academy of Pediatrics

(Member, Committee on Drugs, 1981 -1987)

Canadian Society for Clinical Pharmacology

Canadian Paediatric Society

American Society for Clinical Pharmacology and Therapeutics

President, 2006-2007

Royal College of Physicians and Surgeons of Canada (1983-1992)

ISSX - International Society for the Study of Xenobiotics

Montgomery County and Pennsylvania Medical Societies

#### EDITORIAL POSITIONS:

Editorial Advisory Board, *Pediatric Alert*, 1988-2007

Editorial Board, *Clinical Pharmacology and Therapeutics*, 1988-1998

Section Editor, Toxicology & Clinical Pharmacology, *Current Opinion in Pediatrics*,  
 1988 -1999

Editorial Board, *Pharmacoepidemiology and Drug Safety*, 1991-

Editorial Board, *Therapeutic Drug Monitoring*, 1992-1999

Associate Editor, *Drug Metabolism and Disposition*, 1993-2000

Editorial Board, *Journal of Pediatric Pharmacy Practice*, 1998-

#### GRANT REVIEW COMMITTEES; SCIENTIFIC ADVISORY PANELS:

Medical Research Council of Canada, Pharmacology/Toxicology Grant  
 Review Committee, 1982 - 1987

External Reviewer, National Foundation/March of Dimes, 1981 -  
National Academy of Sciences, National Research Council, Panel on  
Reproductive and Developmental Toxicology, 1986 -1989  
Product Licensing Task Force, Health Protection Branch, 1990 - 1991  
Environmental Hypersensitivity Task Force, Ontario Ministry of Health, 1990 - 1991  
MRC Pharmaceutical Sciences Grant Review Panel, 1991- 1992  
US Pharmacopeia Panel on Drug Utilization Review, 1991-1995  
US Pharmacopeia Panel on Pediatrics, 1996-  
American Society for Clinical Pharmacology and Therapeutics, Committees on  
Nominations and Government Affairs, 1997-2000  
PhRMA, Clinical Steering Committee, Head, Section on Pediatrics, 1997-2003  
Rapporteur, Pediatric ICH E-11 Initiative, 1998-2000  
FDA Pediatric Advisory Subcommittee, 1999-2003  
Advisory Board, PediaLink, AAP On-Line CME Program, 2000-  
External Review Board, Elizabeth Glaser Pediatric Research Network, 2000-  
Federal Advisory Committee, National Children's Study, NICHD. 2002-2003  
Institute of Medicine, NAS, Committee on Research Involving Children, 2002-2004  
Board of Directors, Foundation for the National Institutes of Health, 2002-  
Chair, Pediatric Pharmacology Research Unit Network Advisory Board, NICHD, 2004-  
President, American Society for Clinical Pharmacology and Therapeutics, 2006-7  
Member, Council of the Convention of the United States Pharmacopeia, 2006-  
Member, NIH/NCRR Study Section of Clinical and Translational Science Awards,  
2006-

### PUBLICATIONS

1. Spielberg, S.P., Lucky, A.W., Schulman, J.D., Kramer, L.I., Hefter, L., and Goodman, S.I. Failure of leucovorin therapy in nonketotic hyperglycinemia. *J. Pediatr.* 89, 681, 1976.
2. Butler, J., Spielberg, S.P., and Schulman, J.D. Reduction of disulfide containing amines, amino acids, and small peptides. *Analyt. Biochem.* 75, 674-675, 1976.
3. Pellefigue, F., Butler, J., Spielberg, S.P., Hollenberg, M., Goodman, S.I., and Schulman, J.D. Normal amino acid uptake by cultured human fibroblasts does not require gamma-glutamyltranspeptidase. *Biochem. Biophys. Res. Comm.* 73, 997-1002, 1976.
4. Lucky, A.W., Howley, P.M., Megyesi, K., Spielberg, S.P., and Schulman, J.D. Endocrine studies in cystinosis: Compensated primary hypothyroidism. *J. Pediatr.* 91, 204-210, 1977.
5. Spielberg, S.P. and Schulman, J.D. A possible reaction to pseudoephedrine in a patient with phenylketonuria. *J. Pediatr.* 90, 1026, 1977.
6. Spielberg, S.P., Kramer, L.I., Goodman, S.I., Butler, J., Tietze, F., Quinn, P., and Schulman, J.D. 5-Oxoprolinuria: Biochemical observations and case report. *J. Pediatr.* 91, 237-241, 1977.
7. Butler, J., Tietze, F., Pellefigue, F., Spielberg, S.P., and Schulman, J.D. Depletion of cystine in cystinotic fibroblasts by drugs enclosed in liposomes. *Pediatr. Res.* 12, 46-51, 1978.
8. Spielberg, S.P., Boxer, L.A., Oliver, J.M., Butler, J., and Schulman, J.D. Altered phagocytosis and microtubule function in leukocytes from a patient with severe glutathione synthetase deficiency (5-oxoprolinuria). *Monogr. Hum. Genet.* 9, 90-94, 1978.
9. Oliver, J.M., Spielberg, S.P., Pearson, C.B., and Schulman, J.D. Microtubule assembly and function in normal and glutathione synthetase deficiency. *J. Immunol.* 120, 1181-1186, 1978.
10. Spielberg, S.P., Garrick, M.D., Butler, J., Tietze, F., Corash, L., and Schulman, J.D. Biochemical heterogeneity in glutathione synthetase deficiency. *J. Clin. Invest.* 61, 1417-1420, 1978.
11. Spielberg, S.P., Boxer, L.A., Oliver, J.M., Allen, J.M., and Schulman, J.D. Oxidative

- damage to neutrophils in glutathione synthetase deficiency. *Brit. J. Haematol.* 42, 215-223, 1979.
12. Spielberg, S.P., Boxer, L.A., Corash, L.M., and Schulman, J.D. Improved erythrocyte survival with high dose vitamin E therapy in chronic hemolyzing G6PD and glutathione synthetase deficiencies. *Ann. Intern. Med.* 90, 53-54, 1979.
  13. Kaufman, S., Berlow, S., Summer, G.K., Milstien, S., Schulman, J.D., Orloff, S., Spielberg, S.P., and Pueschel, S. Hyperphenylalaninemia due to a deficiency of bipterin. *N. Engl. J. Med.* 299, 673-679, 1978.
  14. Butler, J. deB. and Spielberg, S.P. Inhibition of gamma-glutamyltranspeptidase by phospholipids and their hydrolytic products. *J. Biol. Chem.* 254, 3152-3155, 1979.
  15. Boxer, L.A., Oliver, J.M., Spielberg, S.P., Allen, J.M., and Schulman, J.D. Protection of granulocytes by vitamin E in glutathione synthetase deficiency. *N. Engl. J. Med.* 301, 901-905, 1979.
  16. Spielberg, S.P., Butler, J. deB., MacDermot, K., and Schulman, J.D. Treatment of glutathione synthetase deficient fibroblasts by inhibiting gamma- glutamyltranspeptidase with serine and borate. *Biochem. Biophys. Res. Comm.* 89, 504-511, 1979.
  17. Spielberg, S.P. Acetaminophen toxicity in human lymphocytes *in vitro*. *J. Pharmacol. Exp. Ther.* 213, 395-398, 1980.
  18. Spielberg, S.P. Glutathione-related disorders, pp. 334-335. In: Schulman, J.D., Moderator. Genetic disorders of glutathione and sulfur amino-acid metabolism: New biochemical insights and therapeutic approaches. *Ann. Intern. Med.* 93, 330-346, 1980.
  19. Corash, L., Spielberg, S.P., Bartsocas, C., Boxer, L., Sheetz, M., Steinhertz, R., and Schulman, J.D. Reduced chronic hemolysis during high dose vitamin E administration in Mediterranean glucose-6-phosphate dehydrogenase deficiency. *N. Engl. J. Med.* 303, 416-420, 1980.
  20. Spielberg, S.P. and McNemar, A. Cystinosis: A Handbook for Parents. NIH Publication No. 82-1160, 1981.
  21. Spielberg, S.P. and Gordon, G.B. Nitrofurantoin cytotoxicity: *In vitro* assessment of risk based on glutathione metabolism. *J. Clin. Invest.* 67, 37-41, 1981.
  22. Spielberg S.P. and Gordon, G.B. Glutathione synthetase deficient lymphocytes and acetaminophen toxicity. *Clin. Pharmacol. Ther.* 29, 51-55, 1981.

23. Gordon, G.B., Spielberg, S.P., Blake, D.A., and Balasubramanian, V. Thalidomide teratogenesis: Evidence for a toxic arene oxide metabolite. *Proc. Nat'l. Acad. Sci.* 78, 2545-2548, 1981.
24. Spielberg, S.P., Gordon, G.B., Blake, D.A., Mellits, E.D., and Bross, D.S. Anticonvulsant toxicity in vitro: Possible role of arene oxides. *J. Pharmacol. Exp. Ther.* 217, 386-389, 1981.
25. Butler, J. DeB. and Spielberg, S.P. Decrease of intracellular cystine content of cystinotic fibroblasts by inhibitors of gamma-glutamyltranspeptidase. *J. Biol. Chem.* 256, 4160-4163, 1981.
26. Spielberg, S.P., Gordon, G.B., Blake, D.A., Goldstein, D.A., and Herlong, H.F. Predisposition of phenytoin hepatotoxicity assessed in vitro. *N. Engl. J. Med.* 305, 722-727, 1981.
27. Spielberg, S.P. Corticosteroids in the prevention of respiratory distress syndrome, in Drugs in Pregnancy, Niebyl, J., Ed., Lea and Febiger, Philadelphia, 1982, pp. 103-114.
28. Spielberg, S.P. Pharmacogenetics and the fetus. *N. Engl. J. Med.* 307, 115-116, 1982 (Editorial).
29. Butler, J. deB. and Spielberg, S.P. Accumulation of cystine from glutathione-cysteine mixed disulfide in cystinotic fibroblasts: blockade by an inhibitor of gamma-glutamyl transpeptidase. *Life Sci.* 31, 2563-2570, 1982.
30. Spielberg, S.P. In vitro human pharmacogenetics of reactive drug metabolite detoxification, in Developmental Pharmacology, MacLeod, S.M., Okey, A.B., and Spielberg, S.P., Eds., Alan R. Liss, Inc., N.Y., 1983, pp. 107-118.
31. Gerson, W.T., Fine, D.G., Spielberg, S.P., Sensenbrenner, L.L. Anticonvulsant-induced aplastic anemia: Increased susceptibility to toxic drug metabolites in vitro. *Blood* 61, 889-893, 1983.
32. Smith, M.K., Kimmel, G., Kochar, D., Shepard, T., Spielberg, S., Wilson, J. A selection of candidate compounds for in vitro teratogenesis test validation. *Teratog. Carcinog. Mutagen.* 3, 461-480, 1983.
33. Shear, N.H. and Spielberg, S.P. Pharmacogenetics and cutaneous adverse drug reactions. *Pediatr. Dermatol.* 1, 165-173, 1983.
34. Leeder, J.S., Spielberg, S.P., MacLeod, S.M. Bendectin: The wrong way to regulate drug

- availability. *Can. Med. Assoc. J.* 129, 1085-1087, 1983.
35. Spielberg, S.P. In vitro assessment of pharmacogenetic susceptibility to toxic drug metabolites in man. *Fed. Proc.* 43, 2308-2313, 1984.
36. Spielberg, S.P. Pharmacogenetic susceptibility to toxic drug metabolites in man, in Banbury Report 16: The Role of Genetic Predisposition in Responses to Chemical Exposure, Cold Spring Harbor Laboratory, N.Y., 1984, pp. 157-166.
37. Spielberg, S.P. Pharmacogenetics, in Textbook of Pediatric Clinical Pharmacology, MacLeod, S.M. and Radde, I.C., Eds., PSG-Wright, Littleton, Mass., 1985, pp. 351-365.
38. Spielberg, S.P. Pharmacogenetics and teratology, in Drugs and Pregnancy, Krauer, B., Krauer, F., Hytten, F.E. and del Pozo, E., Eds., Academic Press, London, 1984, pp. 85-95.
39. Spielberg, S.P. Acetaminophen toxicity in lymphocytes heterozygous for glutathione synthetase deficiency. *Can. J. Physiol. Pharmacol.* 63, 468-471, 1985.
40. Shear, N.H. and Spielberg, S.P. In vitro evaluation of a toxic metabolite of sulfadiazine. *Can. J. Physiol. Pharmacol.* 63, 1370-1372, 1985.
41. Strickler, S.M., Dansky, L.V., Miller, M.A., Seni, M.-H., Andermann, E., and Spielberg, S.P. Pharmacogenetic predisposition to phenytoin-induced birth defects. *Lancet* ii, 746-749, 1985.
42. Dupuis, L. and Spielberg, S.P. Oral decongestants. On continuing practice. 12, 22-24, 1985.
43. Goldstein, D.A., Zimmerman, B., and Spielberg, S.P. Anaphylactic response to hydrocortisone in children. *Ann. Allergy* 55, 559-600, 1985.
44. Spielberg, S.P. and Koren, G. Drugs, chemicals and CNS malformations, in Anomalies of the Developing Central Nervous System: A Comprehensive Approach to Diagnosis and Management, Hoffman, H.J. and Epstein, R., Eds., Blackwell Scientific Publications, Inc., Boston, 1986, pp. 301-312.
45. Pace-Asciak, C.R., Klein, J., and Spielberg, S.P., Metabolism of leukotriene A<sub>4</sub> into C<sub>4</sub> by human platelets. *Biochim. Biophys. Acta* 877, 68-74, 1986.
46. Shear NH, Spielberg SP, Grant DM, Tang BK, Kalow W. Differences in metabolism of

- sulfonamides predisposing to idiosyncratic toxicity. *Ann. Intern. Med.* 105: 179-184, 1986.
47. Pace-Asciak, C.R., Klein, J., and Spielberg, S.P. Human genetic defect in leukotriene C4 synthesis. *Biochem. Biophys. Res. Comm.* 140, 857-860, 1986.
48. Koren, G., Spielberg, S.P., and MacLeod, S.M. Survey of Canadian hospital-based and private pediatricians on clinical pharmacology. *J. Med. Ed.* 61, 769-771, 1986.
49. Vining, E.P.G., Mellits, E.D., Dorsen, M.M., Cataldo, M.F., Quaskey, S.A., Spielberg, S.P., Freeman, J.M. Psychological and behavioral effects of antiepileptic drugs in children: A double blind comparison between phenobarbital and valproic acid. *Pediatr.* 80, 165-174, 1987.
50. Campbell, M.E., Spielberg, S.P., Kalow, W. A urinary metabolite ratio that reflects systemic caffeine clearance. *Clin. Pharmacol. Ther.* 42, 157-165, 1987.
51. Spielberg, S.P. Phenytoin-induced birth defects: The role of pharmacogenetic differences in arene oxide detoxification, in *Pharmacokinetics and Teratogenesis*, Vol. 1, Nau, H. and Scott, W.J., Eds., CRC Press, Boca Raton, 225-232, 1987.
52. Spielberg, S.P. Pharmacogenetic considerations in selection of appropriate animal models in teratogenesis, in *Human Risk Assessment*, Roloff, M.V., Ed., Taylor and Francis, London, 217-228, 1987.
53. Butler, J.D., Key, J.D., Hughes, B.F., Tietze, F., Raiford, D.S., Reed, G.F., Brannon, P.M., Spielberg, S.P., and Schulman, J.D. Glutathione metabolism in normal and cystinotic fibroblast. *Exp. Cell Res.* 172, 158-167, 1987.
54. Rieder, M.J., Uetrecht, J., Spielberg, S.P. Synthesis and toxicity of hydroxylamines of the sulfonamides. *J. Pharmacol. Exp. Ther.* 244, 724-728, 1988.
55. Leeder, J.S., Cannon, M., Nakhooda, A., Spielberg, S.P. Drug metabolite toxicity as assessed in human lymphocytes with a purified, reconstituted cytochrome P-450 system. *J. Pharmacol. Exp. Ther.* 245, 956-962, 1988.
56. Shear, N.H., Spielberg, S.P. Anticonvulsant hypersensitivity syndrome: In vitro assessment of risk. *J. Clin. Invest.* 82, 1826-1832, 1988.
57. Bentur, Y., Koren, G., McGuigan, M., Spielberg, S.P. An unusual skin exposure to copper: clinical and pharmacokinetic evaluation. *J. Clin. Tox.* 26, 371-380, 1988.
58. Rieder, M.J., Uetrecht, J., Shear, N.H., Cannon, M., Miller, M., Spielberg, S.P. Diagnosis of sulfonamide hypersensitivity reactions by in vitro "re-challenge" with

- hydroxylamine metabolites. *Ann. Intern. Med.* 110, 286-289, 1989.
59. Leeder, J.S., Dosch, H.M., Harper, P.A., Lam, P., and Spielberg, S.P. Fluorescence-based viability assay for studies of reactive drug metabolites. *Analytical Biochem.* 177, 364-372, 1989.
60. Koren, G., Bentur, Y., Strong, D., Harvey, E., Klein, J., Bauman, R., Spielberg, S.P., Freedman, M.H. Acute changes in renal function associated with deferoxamine therapy. *Amer. J. Dis. Child.* 143, 1077-1080, 1989.
61. Leeder, J.S., Spielberg, S.P. Teratogenicity and litigation in Maternal-Fetal Toxicology, Koren, G. (ed.) Marcel Dekker, Inc., N.Y., 415-425, 1989.
62. Koren G., Demitakoudis D., Weksberg R., Rieder M., Shear N., Sonely M., Shandling B., Spielberg S. Neuroblastoma after prenatal exposure to phenytoin: cause and effect? *Teratology* 40, 157-162, 1989.
63. Cribb, A.E., Leeder, J.S., Spielberg, S.P. Use of a microplate reader in an assay of glutathione reductase using 5,5'-dithiobis (2-nitrobenzoic acid). *Analyt. Biochem.* 183, 195-196, 1989.
64. Roberts E.A., Spielberg S.P., Goldbach M., Phillips M.J. Phenobarbital hepatotoxicity in an eight month-old infant. *J. Hepatol.* 10, 235-239, 1990.
65. Spielberg, S.P. Toxicology and clinical pharmacology: An editorial overview. *Current Opinion in Pediatrics* 2, 217-220, 1990.
66. Spielberg, S.P., Toxicology and clinical pharmacology, (editor). *Current Opinion in Pediatrics* 2, 217-271, 1990.
67. Cribb, A.E., Spielberg, S.P. An *in vitro* investigation of predisposition to sulfonamide idiosyncratic toxicity in dogs. *Vet. Res. Comm.* 14, 241-252, 1990.
68. Levy, M., Duffy, C. Pollak, P., Budd E., Spielberg, S.P., Koren, G. Home-based palliative care for children. I. Institution of a program. *J. Palliative Care* 6(1), 11-15, 1990.
69. Duffy, C., Pollak, P., Levy, M., Budd, E., Spielberg, S.P., Koren, G. Home-based palliative care for children. II. Benefits of an established program. *J. Palliative Care* 6(2), 8-14, 1990.
70. Cribb, A.E., Spielberg, S.P. Hepatic microsomal metabolism of sulfamethoxazole to the hydroxylamine. *Drug Metab. Disp.* 18, 784-787, 1990.

71. Spielberg, S.P. Pathogenesis and pharmacogenetics of idiosyncratic hypersensitivity adverse drug reactions, in Idiosyncratic Drug Reactions: Impact on Drug Development and Clinical Use After Marketing, Naranjo, C.A., Jones, J.K. (eds.), Elsevier Science Publishers, B.V., Amsterdam, 1990, pp.145-158.
72. Grant, D., Spielberg, S.P. Genetic regulation of drug metabolism, in Fetal and Neonatal Physiology, Polin, R.A. and Fox, W.W., Eds., W. B. Saunders, Philadelphia, pp. 141-148, 1992.
73. Cribb, A. E., Miller, M., Tesoro, A., Spielberg, S. P. Peroxidase-dependent oxidation of sulfonamides by monocytes and neutrophils from man and dog. Mol. Pharmacol. **38**, 744-751, 1990.
74. Lambert, G.H., Schoeller, D.A., Humphrey, H.E.B., Kotake, A.N., Lietz, H., Campbell, M., Kalow, W., Spielberg, S.P., Budd, M. The caffeine breath test and caffeine urinary metabolite ratios in the Michigan cohort exposed to polybrominated biphenyls: A preliminary study. Environ. Health Perspect. **89**, 175-181, 1990.
75. Riley, R.J., Leeder, J.S., Dosch, H.-M., Spielberg, S.P. Interactions between N-acetyl-p-benzoquinone imine and fluorescent calcium probes: Implications for mechanistic toxicology. Analyt. Biochem. **191**, 253-261, 1990.
76. Rieder, M.J., Shear, N.H., Kanee, A., Tang, B.K., Kalow, W., Spielberg, S.P. Predominance of slow acetylator phenotype among patients with sulfonamide hypersensitivity reactions. Clin. Pharmacol. Ther. **49**, 13-17, 1991.
77. Zalstein, E., Spielberg, S.P. Principles of pediatric therapeutics, in Pediatric Gastroenterointestinal Disease, Walker, W.A., Drurie, P.R., Hamilton, J.R., Walker-Smith, J.A., Watkins, J.B., eds., B.C. Decker, Toronto, pp. 1689-1694, 1991.
78. Roberts, E.A., Spielberg, S.P. Drug-induced liver injury, in Pediatric Gastroenterointestinal Disease, Walker, W.A., Drurie, P.R., Hamilton, J.R., Walker-Smith, J.A., Watkins, J.B., eds., B.C. Decker, Toronto, pp. 898-914, 1991.
79. Leeder, J.S., Dosch, H.-M., Spielberg, S.P. Cellular toxicity of sulfamethoxazole reactive metabolites: 1. Inhibition of intracellular esterase activity precedes cell death. Biochem. Pharm. **41**, 567-574, 1991.
80. Leeder, J.S., Nakhoda, A., Spielberg, S.P., Dosch, H.-M. Cellular toxicity of sulfmethoxazole reactive metabolites: II. Inhibition of natural killer activity in human peripheral blood mononuclear cells. Biochem. Pharm. **41**, 575-583, 1991.

81. Spielberg, S.P., Shear, N.H., Cannon, M., Hutson, N.J., Gunderson, K. *In vitro* assessment of hypersensitivity reactions to Sorbinil. *Ann. Intern. Med.* 114, 720-724, 1991.
82. Spielberg, S.P. Toxicology and clinical pharmacology. An editorial overview. *Current Opinion in Pediatrics* 3, 281-282, 1991.
83. Spielberg, S.P. (ed.) Toxicology and clinical pharmacology. *Current Opinion in Pediatrics* 3, 281-321, 1991.
84. Riley, R., Cribb, A.E., Spielberg, S.P. Glutathione-S-transferase mu is not a marker for sulfonamide hypersensitivity reactions. *Biochem. Pharm.* 42, 696-698, 1991.
85. Cribb, A.E., Miller, M.A., Leeder, J.S., Spielberg, S.P. Reactions of the nitroso and hydroxylamine metabolites of sulfamethoxazole with reduced glutathione: Implications for idiosyncratic toxicity. *Drug Metab. Disp.* 19, 900-906, 1991.
86. Cribb, A.E., Grant, D.M., Spielberg, S.P. Expression of the monomorphic arylamine N-acetyltransferase (NAT1) in human leukocytes. *J. Pharmacol. Exp. Ther.* 259, 1241-1246, 1991.
87. Gennis, M.A., Vemuri, R., Burns, E.A., Hill, J.V., Miller, M.A., Spielberg, S.P. Familial occurrence of phenytoin hypersensitivity. *Amer. J. Med.* 91, 631-634, 1991.
88. Spielberg, S.P., Grant, D.M. Pharmacogenetics and biologic markers of unintended drug effects, in *Pharmacoepidemiology - An Introduction*, 2nd. Ed., Hartzema, A.G., Porta, M.S., Tilson, H.H., eds., Harvey Witney Books, Cincinnati, 1991, pp.18-35.
89. Gupta, A., Eggo, M.C., Uetrecht, J.P., Cribb, A.E., Daneman, D., Rieder, M.J., Shear, N.H., Cannon, M., Spielberg, S.P. Drug-induced hypothyroidism: The thyroid as a target organ in hypersensitivity reactions to anticonvulsants and sulfonamides. *Clin. Pharmacol. Ther.* 51: 56-67, 1992.
90. Spielberg, S.P. Toxicology and clinical pharmacology -Editorial overview. *Current Opinion in Pediatrics* 4: 277-278, 1992.
91. Spielberg, S.P. (ed.) Toxicology and clinical pharmacology. *Current Opinion in Pediatrics* 4: 277-326, 1992.
92. Spielberg, S. P. Idiosyncratic drug reactions: Interaction of development and genetics, in *Seminars in Perinatology* 16: 58-62, 1992.
93. Spielberg, S.P. Pediatric therapeutics and drug utilization (editorial). *Pharmacoepidemiology and Drug Safety* 1: 31-32, 1992.

94. Cribb, A.E., Spielberg, S.P. Sulfamethoxazole is metabolized to the hydroxylamine in humans. *Clin.Pharmacol. Ther.* 51, 522-526, 1992.
95. Spielberg, S.P. Subpopulation risk: Interaction of development and genetics, in *Similarities and Differences between Children and Adults: Implications for Risk Assessment*. P.S. Guzelian, C.J. Henry, and S.S. Olin, eds. ILSI Press, Washington, D.C., 1992, pp. 16-23.
96. Spielberg, S.P., Tolbert, J.A. HMG CoA reductase inhibitors and sleep. *Clin. Pharmacol. Ther.* 52: 109-111, 1992.
96. Spielberg, S.P. Anticonvulsant ADRs: Age-dependent and age-independent, in *Similarities and Differences between Children and Adults: Implications for Risk Assessment*. P.S. Guzelian, C.J. Henry, and S.S. Olin, eds. ILSI Press, Washington, D.C., N.J., 1992, pp. 104-106.
97. Leeder, J.S., Riley, R.J., Cook, V.A., Spielberg, S.P. Human anti-cytochrome P-450 antibodies in aromatic anticonvulsant-induced hypersensitivity reactions. *J. Pharmacol. Exp. Ther.* 263, 360-367, 1992.
98. Spielberg, S. P. Populations at risk: Predicting and preventing drug-induced disease. *Pharmacoepidemiology and Drug Safety* 2: S31-S36, 1993.
99. Uetrecht, J. P., Spielberg, S. P. Mechanisms of neutropenia: The role of neutrophil-specific pathways of drug metabolism. *Pharmacoepidemiology and Drug Safety* 2: S37-S42, 1993.
100. Spielberg, S.P. Therapeutics and Toxicology. Editorial Overview. *Current Opinions in Pediatrics* 5: 199-200, 1993.
101. Spielberg, S.P.(ed) Therapeutics and Toxicology. *Current Opinions in Pediatrics* 5, 199-226, 1993.
102. Cribb, A.E., Nakamura, H., Grant, D.M., Miller, M.A., Spielberg, S.P. Role of polymorphic and monomorphic human arylamine N-acetyltransferases in determining sulfamethoxazole metabolism. *Biochem. Pharmacol.* 45, 1277-1282, 1993.
103. Grant, D.M., Spielberg, S.P. Pharmacogenetics, in *Pediatric Pharmacology and Therapeutics*, 2nd, Ed., I.C. Radde and S.M. MacLeod, eds., Mosby-Year Book, Inc., St. Louis, 1993, pp. 466-474.
104. Riley, R.J., Spielberg, S.P., Leeder, J.S. A comparative study of the toxicity of chemically reactive xenobiotics towards adherent cell cultures: Selective attenuation of menadione toxicity by buthionine sulfoximine pretreatment. *J. Pharm. Pharmacol.* 45, 263-267,

- 1993.
105. Spielberg, S.P. Therapeutics and Toxicology. Editorial Overview. *Current Opinion in Pediatrics* 6, 201-202, 1994.
106. Spielberg, S.P. (ed) Therapeutics and Toxicology. *Current Opinion in Pediatrics* 6, 201-217, 1994.
107. Gaedigk, A., Spielberg, S.P., Grant, D.M. Characterization of the microsomal epoxide hydrolase gene in patients with anticonvulsant adverse drug reactions. *Pharmacogenetics* 4: 142-153, 1994.
108. Jacobson, S.J., Shore, R.W., Greenberg, M., Spielberg, S.P. The efficacy and safety of granisetron in pediatric cancer patients who had failed standard antiemetic therapy during anticancer chemotherapy. *Amer. J. Pediatr. Hematol/Oncol.* 16: 231-235, 1994.
109. Naranjo, C.A., Kwok, M., Lactot, K.L., Zhao, H., Spielberg, S.P., Shear, N.H. Enhanced differential diagnosis of anticonvulsant hypersensitivity reactions by an integrated Bayesian and biochemical approach. *Clin. Pharmacol. Ther.* 56, 564-575, 1994.
110. Cribb, A.E., Griffin, G.P., Spielberg, S.P., Rushmore, T.H., Chauret, N., Nicoll-Griffith, D.A. Increased cosedimentation of cytosolic glutathione-S-transferases with microsomal fractions prepared from frozen rat liver. *Drug Metab. Disp.* 22, 969-972, 1994.
111. Cribb, A.E., Spielberg, S.P., Griffin, G.P. N4-Hydroxylation of sulfamethoxazole by cytochrome P450 of the CYP2C subfamily, and reduction of sulfamethoxazole hydroxylamine in human and rat hepatic microsomes. *Drug Metab. Disp.* 23, 406-414, 1995.
112. Spielberg, S.P. Therapeutics and toxicology. Editorial Overview. *Current Opinion in Pediatrics* 7, 193-194 1995.
113. Spielberg, S.P. (ed) Therapeutics and toxicology. *Current Opinion in Pediatrics* 7, 193-233, 1995.
114. Nakamura, H., Utrecht, J., Cribb, A.E., Miller, M.A., Hill, J., Josephy, F.D., Grant, D.M., and Spielberg, S.P. *In vitro* formation, disposition and toxicity of N-acetoxysulfamethoxazole, a potential mediator of sulfamethoxazole toxicity. *J. Pharmacol. Exp. Ther.* 274, 1099-1104, 1995.
115. Spielberg, S.P. Pharmacogenetics: From scientific curiosity to a central theme in drug development and therapeutics. The 1995 Werner Kalow Lecture, *Can. J. Clin. Pharm.* 2, 54-56, 1995.

116. Nies, A.S., Spielberg, S.P. Principles of therapeutics, in Goodman and Gilman's The Pharmacological Basis of Therapeutics, 9th Ed., J.G. Hardman and L.E. Limbird, eds., McGraw-Hill, Inc, 1996, pp.43-63.
117. Cribb, A.E., Nuss, C.E., Alberts, D.W., Lamphere, D.B., Grant, D.M., Grossman, S.J., Spielberg, S.P. Covalent binding of sulfamethoxazole reactive metabolites to human and rat liver subcellular fractions assessed by immunochemical detection. *Chem. Res. Toxicol.* 9, 500-507, 1996.
118. Cribb, A.E., Lee, B.L., Trepanier, L.A., Spielberg, S.P. Adverse reactions to sulfonamide and sulfonamide-trimethoprim antimicrobials: Clinical syndromes and pathogenesis. *Adverse Drug Reactions and Toxicological Reviews* 15, 1-42, 1996.
119. Roberts, E.A., Spielberg, S.P. Drug-induced hepatotoxicity in children, in Pediatric Gastrointestinal Disease, Walker, W.A., Durie, P.R., Hamilton, J.R., Walker-Smith, J.A., Watkins, J.B., eds., Mosby, 1996, pp.1083-1101.
120. Spielberg, S.P. N-acetyltransferases: Pharmacogenetics and clinical consequences of polymorphic drug metabolism. *J. Pharmacokinetics and Biopharm.* 24, 509-519, 1996.
121. Spielberg, S.P. Pharmacogenetics and blood dyscrasias. *Eur. J. Haematol.* 57(Suppl), 93-98, 1996.
122. Spielberg, S. P. Opportunities for pediatric drug development: The knowledge bridge from basic science to clinical application. *Drug Information J.* 30, 1145-1148, 1996.
123. Trepanier, L.A., Winand, N., Spielberg, S.P., Cribb, A.E. Cytosolic arylamine N-acetyltransferase deficiency in the dog and other canids due to an absence of NAT genes. *Biochem. Pharmacol.* 54, 73-80, 1997.
124. Cribb, A.E., Pohl, L.R., Leeder, J.S., Spielberg, S.P. Patients with delayed onset sulfonamide hypersensitivity reactions have antibodies recognizing endoplasmic reticulum luminal proteins. *J. Pharmacol. Exp. Ther.* 282, 1064-1067, 1997.
125. Trepanier, L.A., Cribb, A.E., Spielberg, S.P., Ray, K. Deficiency of cytosolic arylamine N-acetyltransferase in the domestic cat and wild felids caused by the presence of a single NAT1-like gene. *Pharmacogenetics* 8, 169-179, 1998.
126. Spielberg, S.P. Therapeutics and toxicology, Editorial Overview. *Current Opinion in Pediatrics* 10, 201-202, 1998.
127. McCrea, J.B., Cribb, A.E., Rushmore, T., Osborne, B., Gillen, L., Lo, M.-L., Waldman, S., Bjornsson, T., Spielberg, S.P., Goldberg, M.R. Phenotypic and genotypic investigations of

- a healthy volunteer deficient in the conversion of losartan to its active metabolite E-3174. *Clin. Pharmacol. Ther.* 65: 348-352, 1999.
128. Knorr, B., Larson, P., Nguyen, H.H., Holland, S., Reiss, T.F., Chervinsky, P., Blake, K., Nispen, C.H.M., Noonan, G., Freeman, A., Haesen, R., Michiels, N, Rogers, D., Amin, R.D., Zhao, J., Xu, X., Seidenberg, B.C., Gertz, B.J., Spielberg, S.P. Montelukast dose selection in 6-14 year-olds: Comparison of single-dose pharmacokinetics in children and adults. *J. Clin. Pharmacol.* 39: 786-793, 1999.
129. Spielberg, S.P. Paediatric therapeutics in the USA and internationally: An unparalleled opportunity. *Paediatric and Perinatal Drug Therapy* 4: 71-74, 2000.
130. Spielberg, S.P. Pediatric therapy for the new millenium. *J. Pediat. Pharmacol. and Therap.* 6: 6-9, 2001.
131. Spielberg, S.P., Knorr, B.K., Nguyen, H.H., Kearns, G.L., Villaran, C., Boza, M.L., Reiss, T.F., Rogers, J.D., Zhang, J., Larson, P. Montelukast dose slection in children 2 to 5 years: Comparison of population pharmacokinetics between children and adults. *J. Clin. Pharmacol.* 41: 612-619, 2001.
132. Abdel-Rahman SM, Leeder JS, Wilson JT, Gaedigk A, Gotschall RR, Medve R, Liao S, Spielberg SP, Kearns GL. Concordance between tramadol and dextromethorphan parent/metabolite ratios: the influence of CYP2D6 and non-CYP2D6 pathways on biotransformation. *J. Clin. Pharmacol.* 42:24-29, 2002.
133. Kearns, GL, Ritschel, WA, Wilson, JT, Spielberg, SP. Clinical Pharmacology: A discipline called to action for maternal and child health. *Clin. Pharm. Therap.* 81: 463-468, 2007.

