

Consulting services offered:

- Preparation of INDs and NDAs for a variety of products: IUDs and oral contraceptives, CNS drugs, Cardiovascular drugs, anti-inflammatory drugs.
- Production of medical information and medical education materials from clinical study reports
 - Medical education slides and figures for clinical and non-clinical publications (have prepared slides and figures from clinical studies for Ambien, women's health products, Celebrex, Bextra, others)
- Manuscript writing from clinical trials; review papers
- New product evaluation and product evaluation for inlicensing
- Clinical study design
- Litigation support involving
 - Use/abuse of CNS drugs, particularly hypnotics (drugs for sleep), alcohol, and antidepressants
 - Effects of COX-2 inhibitors (Celebrex, Bextra)
 - Contraceptive litigation
 - Use of illegal drugs
 - Adverse effects of dietary supplements
 - Misoprostol in abortion

Curriculum Vitae

Employment history

Pharmaceutical Consultant; BJ Struthers, Ltd. 2001-present. President, Pharmaceutical consulting services company. Wrote a large part of NDA for doxepin for insomnia, currently under FDA review, also for nalmefene. Literature searches and summaries for doxepin, nalmefene, bupropion, and nicotine stop-smoking products. Production of medical information letters, statements, and slides; preparation of medical education materials including slides from clinical studies, in-license product candidate evaluation, clinical study design; consultant for establishing of and improving medical information functions in pharmaceutical companies; write product monographs. Write scientific sections of annual reports.

Products: anti-inflammatory drugs (celecoxib, valdecoxib; pexelizumab; oncology drugs (bortezomib, celecoxib, IL13-PE38QQR, LERAF-AON,); CNS drugs (zolpidem, doxepin for sleep, nalmefene,); women's health products: oral and intrauterine contraceptives, nafarelin acetate, misoprostol; others

Litigation support, including evaluations and provision of professional opinion of alcohol and illicit substance consumption based on medical and laboratory records, and of prescription products including sleep products.

Discovery International, Deerfield, IL. 2000-2001. Vice president, scientific and editorial services. Directed work of 11 medical writers in producing symposia, slide kits, monographs, executive summaries for pharmaceutical company advisory board and consultant meetings. Responsible for scientific content of marketing requests for proposal.

Searle, Skokie, IL, 1982 - 2000

1995-2000: Medical Director, Healthcare Information Services. As Medical Director for Ambien, was involved in design and analysis of zolpidem clinical trials and in receiving and analyzing adverse experiences with zolpidem. Responsible for medical information and support of Medical Affairs Managers for therapeutic areas of Sleep, Oncology, and Women's Health. Initiated medical information for Ambien and for Celebrex oncology, assembled and presented CME programs in both sleep and oncology.

Litigation support, especially Ambien and women's health products.

1991-1995: Senior Scientific Advisor, Corporate Medical & Scientific Affairs, Directed Phase 3 and 3A clinical studies and grant programs; Regulatory approval committee. Litigation support for women's health products, metronidazole, misoprostol.

1988-1991: Director, Gastrointestinal and Anti-infective Products, Office of Scientific Support Designed and directed clinical trials; Litigation support for women's health products, metronidazole, misoprostol for inside and outside counsel.

1987-1988: Director, Gynecologic Products, Office of Scientific Support.

Responsibilities (1987 ff.): Responsible for adverse drug reactions for Searle drugs. Served as consultant and technical advisor to product liability attorneys (inside and outside counsel). Reviewed hundreds of medical records, and set up scientific defense for IUD (Cu-7) litigation. Testified at trials and in depositions.

Regulatory approval committee.

1982-1987: Assoc. Director, Office of Scientific Affairs.

Regulatory approval committee, litigation support for product liability legal staff; Testify at trials and in depositions. new drug evaluation.

1973-1982: Ralston Purina Company, St. Louis, MO.

1981-1982: Manager of Toxicology, Pathology/Toxicology Group - Eight professional employees.

Summary of Responsibilities, 1973-1982: Provide professional direction and leadership for soy protein product safety effort and toxicology group. Member of corporate long range planning committees. Wrote and directed research projects in biochemical toxicology relating to soy protein production. Coordinated research efforts of corporate and divisional groups, and analytical and animal laboratories. Consultant to divisional groups and analytical labs. Wrote and directed research projects in food oil chemistry and biochemical toxicology.

Other Major Responsibility: 1974-1982 Served as Radiation Safety Officer for Corporate and divisional research groups.

EDUCATION

Board certification, American Board of Toxicology: Since 1981

Ph.D. - Major: Food Science. Minors: Biochemistry, Pharmacology 1970-1973. Oregon State University, Corvallis, OR. National Science Foundation Graduate Research Fellow.

M.S. - Major: Biochemistry. Minor: Education. Oregon State University, Corvallis, OR. 1967-1968.

B.S. - Highest honors. Majors: Biology, Education. Minor: Chemistry. Washington State University, Pullman, Washington. Honors & Awards: NIH Undergraduate Research Fellow, Phi Beta Kappa, Phi Kappa Phi, Pi Lambda Theta (education). Outstanding student, College of Arts & Sciences.

PROFESSIONAL ACTIVITIES

Midwest Chapter, Society of Toxicology: Secretary, 2004-6; President, 1992-3; Pres.-elect, 1991-2; Councilor, 1987-89; Society of Toxicology, ethics committee, 1987-89.

Society for Advancement of Contraception Board of Directors, (1988 - 2000); Chairman, annual meeting of Society for Advancement of Contraception, 1986

Industry Liaison committee, American Institute of Nutrition, 1994 - 1999.

MEMBERSHIPS AND AFFILIATIONS IN PROFESSIONAL ORGANIZATIONS

American Institute of Nutrition

American Oil Chemists' Society

Sigma XI

Teratology Society

Phi Beta Kappa

American Association for the Advancement of Science

*past board member ** past president, current secretary

Society for Advancement of Reproductive Health*

Society of Toxicology

Midwestern Regional Society of Toxicology**

Iota Sigma Pi

Association of Reproductive Health Professionals

COMMUNITY ACTIVITIES

Trustee, Village of Deerfield since 2005

Trustee, Southlake Mosquito Abatement District

Past president, Deerfield Rotary Club

Member, Village Center Development Commission, 18 years

15-year volunteer, Recording for the Blind and Dyslexic (4 years on governing board)

League of Women Voters

North Shore Choral Society member since 1983

HONORS AND AWARDS

"Woman of Excellence" award from Deerfield AAUW chapter (a 50th anniversary award)

Kenneth A. Dubois award from Midwest Regional Society of Toxicology for contributions to toxicology

PUBLICATIONS

Wrolstad, R. E. and B. J. Struthers. Polyvinylpyrrolidone column chromatography of strawberry, rhubarb, and raspberry anthocyanins. J. Chromatog. 55:405-408 (1971).

Struthers, B. J., D. J. Lee and J. H. Wales. Hepatic phospholipid turnover inhibition by sterculic acid in rainbow trout. Fed. Proc. 32:277 abs (1973).

Struthers, B. J., J. H. Wales, D. J. Lee, and R. O. Sinnhuber. Liver composition and histology of rainbow trout fed cyclopropenoid fatty acids. Exp. Molec. Pathol. 23:164-170 (1975).

Struthers, B. J., D. J. Lee, and R. O. Sinnhuber. Altered lipid metabolism in livers of rainbow trout fed cyclopropenoid fatty acids. Exp. Molec. Pathol. 23:181-187 (1975).

- Struthers, B. J., R. R. Dahlgren and D. T. Hopkins. Biological effects of feeding graded levels of alkali-hydrolyzed soy protein containing lysinoalanine (N,-DL-[2-amino-2-carboxyethyl]-L-lysine, LAL) in Sprague-Dawley and Wistar rats. *Fed. Proc.* 35:497 abs (1976).
- Hopkins, D. T., Armstrong, D. J., B. J. Struthers, M. S. Cover and K. E. Rinehart. Factors Influencing the incidence of gizzard erosion in chicks. *Poult. Sci. Ann. Meeting*, 1976. Kansas State Univ., Manhattan KS, Aug 2-6 (1976).
- Struthers, B. J., R. R. Dahlgren and D. T. Hopkins. Biological effects of feeding graded levels of alkali treated soybean protein containing lysinoalanine (N,-D,L-[2-amino-2-carboxyethyl]-L-lysine) (LAL) in Sprague-Dawley and Wistar rats. *J. Nutr.* 107:1190-1199 (1977).
- Struthers, B. J., D. T. Hopkins and R. R. Dahlgren. Reversibility of nephrocytomegaly caused in rats by lysinoalanine (N,-DL-[2-amino-2-carboxyethyl]-L-lysine.) *J. Food Sci.* 43:616-618 (1978).
- Struthers, B. J., D. T. Hopkins, E. E. Prescher, and R. R. Dahlgren. Effects of protein-bound lysinoalanine, N,-DL-[2-amino-2-carboxyethyl]-L-lysine) on fetal and neonatal rats. *J. Nutr.* 108:954-958 (1978).
- Struthers, B. J., J. R. Brielmaier and D. T. Hopkins. Excretion and tissue distribution of ¹⁴C-lysinoalanine, (N,-DL-[2-amino-2-carboxyethyl]-L-lysine, LAL, in rats. *Fed. Proc.* 37:505 abs, (1978).
- Struthers, B. J., J. R. Brielmaier, R. R. Dahlgren, M. L. Raymond and D. T. Hopkins. Excretion of ¹⁴C-lysinoalanine (LAL) by control and LAL-prefed rats. *Fed. Proc.* 37: (1978).
- Struthers, B. J., R. R. Dahlgren, D. T. Hopkins, and M. L. Raymond. Lysinoalanine: Biological Effects and Significance. In: *Soy Protein and Human Nutrition*. pp 235-260 (1979) (Ed: H. Wilcke, D. T. Hopkins, and D. H. Waggle).
- Van Kley, H., Doub, C. M. and Struthers, B. J. Incomplete inhibition of trypsin in duodenal aspirates. *American Pancreatic Assoc. Meeting*, paper No. 30, November 1979, Chicago, IL.
- Struthers, B. J., J. R. Brielmaier, M. L. Raymond, R. R. Dahlgren and D. T. Hopkins. Excretion and Tissue Distribution of Radioactive Lysinoalanine, N,-DL-(2-amino-2-carboxyethyl)-L- U-¹⁴C-lysine (LAL) in Sprague-Dawley rats. *J. Nutr.* 110:2065-2077 (1980).
- Struthers, B. J., J. R. Brielmaier, D. T. Hopkins and H. Van Kley. Effect of feeding diets containing soybean trypsin inhibitor (TI) to monkeys, and comparative inhibition of human, monkey and other trypsins by Soy TI. *Fed. Proc.* 39:377a (1980).
- Struthers, B. J., J. R. Brielmaier and D. F. Feller. Species comparison of responses to raw soy flour (RSF) and cholecystokinin (CCK). *American Pancreatic Assoc. Meeting abstracts*, p.56, (1981).
- Struthers, B. J., Lysinoalanine production, significance, and control in preparation and use of soya and other food proteins. *J. Am. Oil Chem. Soc.* 58:501-503 (1981).
- Struthers, B. J., MacDonald, J. B., Dahlgren, R. R., and Hopkins, D. T. Effects on monkey, pig, and rat pancreas of soy products with varying levels of trypsin inhibitor, and comparison with administration of cholecystokinin. *J. Nutr.* 113:(1) 86-97 (1983).
- Struthers, B. J. and J. R. MacDonald. Comparative inhibition by soybean trypsin inhibitor of trypsins and pancreatic proteolytic activity in several species. *J. Nutr.* 113:800-804 (1983).
- Struthers, B. J., J. R. MacDonald, E. E. Prescher, and D. T. Hopkins. Influence of several plant and animal proteins and fats on rat pancreas. *J. Nutr.* 113:1503-1512 (1983).

Struthers, B. J. The Industry point of view: Intrauterine contraception, the medical literature, and sexually transmitted disease. Presented at 1st annual meeting, Society for Advancement of Contraception, Cairo, Egypt November 5-9, (1983).

Struthers, B. J. Comparative Response of Rats, Monkeys and Pigs to Raw or Heated soy Flour or Casein Diets and Cholecystokinin Injection. J. Am Oil Chem. Soc. 61: 683 (1984) (Abs. 182).

Struthers, B. J. and F. B. O'Brien. IUDs and Ectopic Pregnancy. Presented at the First Annual Meeting of the Fallopius Society, Kiawah Is, S. C. Sept 9-11 (1984).

Struthers, B. J. Pelvic inflammatory disease, intrauterine contraception, and the conduct of epidemiologic studies. Adv. Contracept. 1: 61-74 (1985).

Struthers, B. J., M. Harvey, and E. Young. Contributions of an outside expert to a high school sexually transmitted disease program. Adv. Contracept. 1(3): abs. (1985).

Struthers, B. J., and J. R. MacDonald. Effects of raw soy flour feeding in weanling pigs: comparison with rats and monkeys. Qual. Plant Foods Hum. Nutr. 35:331-338 (1985).

Struthers, B. J. and Parr, R. J. Letter to the editor: Clarifying the metronidazole hydrochloride-aluminum interaction. Am J Hosp Pharm 42: 2660 (1985).

Struthers, B. J. IUD Update. Presented at: International Society for Reproductive Medicine, Annual Meeting, Augusta, GA November, (1985).

Struthers, B. J., F. B. O'Brien, and W. C. Stewart. Ectopic pregnancy in women using IUDs. In: Siegler, A., ed. The Fallopian Tube: Basic Studies and Clinical Contributions. Mt. Kisco, NY, Futura Pub., (1986).

Struthers, B. J. Warning: Feeding animals hydrophilic fiber sources in dry diets. J. Nutr. 116: 47-49 (1986).

Struthers, B. J. Sexually Transmitted Disease, Infertility, IUDs, and Epidemiologic Studies. Adv. Contracept. 3: 82-96 (1987).

Struthers, B. J. Intrauterine Contraception, PID, and Infertility. In: Asch, R., ed., Recent Advances in Human Reproduction, Fondazione per GLI Studi sulla Riproduzione Umana, pp 323-332 (1987).

Struthers, B. J. Letter to the editor: Quantitative transcervical uterine cultures in asymptomatic women using an Intrauterine Contraceptive device. Obstet Gynecol 70: 429-430 (1987).

Struthers, B. J. Epidemiology: IUDs, PID, and Infertility. Adv. Contracept. 3: 189 (1987). Abstr. #27. Presented at the Fifth Annual Meeting of the Society for Advancement of Contraception, Caracas, Venezuela, Oct. 5-8, (1987).

Struthers, B. J. Effects of using IUDs: A review of some epidemiological and vital statistical data. Brit. J. Fam. Plan. 13:28-34 (1988). (Presented at the 15th Annual Meeting of The British Association of Family Planning Doctors, London, England, Oct 28-30 (1987).

Struthers, B. J. IUDs, sexually transmitted disease, and infertility. In: Takagi, S and Zatuchni, G I, eds., Human Reproduction and Contraception. PPS, Japan, 1988, pp 192-194. Presented at the 6th annual meeting of the Society for Advancement of Contraception, Tokyo, Japan, May 23-26, 1988.

Struthers, B. J. Comparison of PID rates in parous and nulliparous women using copper IUDs: summary of clinical studies. Adv. Contracept. 6:257 (Abs 47), 1990.

Struthers, B. J. Incidence of Chlamydia, other STDs, PID and sexual behavior in women of various age groups. Adv. Contracept. 6:273 (Abs 68), 1990.

Struthers, B. J. Copper IUDs, PID, and fertility in nulliparous women: A review of literature. Adv. Contracept., 7: 211-230, 1991.

Silverstein FE, Graham DY, Senior JR, Davies HW, Struthers BJ, Bittman RM, Geis GS. Misoprostol reduces serious gastrointestinal complications in patients with rheumatoid arthritis on nonsteroidal anti-inflammatory drugs. Ann. Int. Med. 123: 241 - 249, 1995.

Struthers BJ, Shield MJ. Overview: Misoprostol and Eicosanoids. Am J. Therapeutics, 1995, 2:595-599.

Struthers, BJ. Metronidazole does not appear to be a human teratogen. Infect Dis Obstet Gynecol 5:326-335 (1997).

Struthers, BJ. Position paper for REP-America: environmental mercury.

U.S. PATENTS

5,213,807; 5,601,843 (Arthrotec)

