

Marilyn Barrett PhD

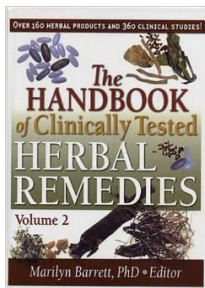
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Expertise: Marilyn Barrett PhD is a leading edge, internationally-recognized expert in the botany, chemistry and pharmacology of medicinal plants.

Pharmacognosy Consulting: Founded 1995, Incorporated in California 2012
As founder and principal of Pharmacognosy Consulting, Marilyn has served the dietary supplement & botanical drug industries for the past 29 years. She is known for her creative approach to rigorous scientific inquiry, the caliber of teams she assembles when needed, and for being beyond reproach in the standards to which she adheres. Dr. Barrett is dedicated to advancing standards of excellence for botanically-based products through compiling scientific evidence of safety and efficacy.

Author: *The Handbook of Clinically Tested Herbal Remedies*. Volumes I and II. Taylor & Francis (Haworth Press), 2004, 1400 pg. is a reference tool designed to highlight herbal products that have been tested clinically. The book includes a snapshot in time of 30 individual botanicals, 10 multi-ingredient formulas and 160 products that were tested in human clinical trials. An evaluation of the strength of the evidence from 360 clinical trials, along with a context for therapeutic usefulness or lack thereof is included. The book opens with a description of the fundamentals of herbal medicine: regulation, characterization, standardization, bioavailability, efficacy, safety, pharmacopeial monographs as well as incentives, or lack of incentive, for US and European manufacturers to conduct clinical studies. The book was a collaborative effort with 13 colleagues assisting in the writing of the fundamental chapters and 14 colleagues in reviewing the quality of the clinical studies.



BA Botany: University of California, Berkeley, CA, 1977

PhD Pharmacognosy: University of London School of Pharmacy, London, UK, 1985.

Adjunct Professor: Touro University-California College of Pharmacy: Lecturer in Pharmacognosy, 2009 to present

Advisory Roles: Marilyn is a member of the American Botanical Council Advisory Board, the American Herbal Pharmacopoeia and Therapeutic Compendium Technical Advisory Board, and the American Herbal Products Association's Scientific Advisory Board. She was a member of the United States Pharmacopoeia Committee of Experts on Dietary Supplements from 2000 to 2015.

Efficacy Profiles: Dr. Barrett is experienced in compiling scientific literature reviews documenting support for dietary supplement claims statements. She has critically reviewed clinical studies for her book, referenced above. Marilyn has also documented efficacy for a start-up pharmaceutical company in its Investigational New Drug (IND) application to the FDA.

Safety Reviews: Dr Barrett is experienced in the compilation of safety reviews used to determine the safety of herbal substances as ingredients in dietary supplement. She has both written dossiers and served as an expert for Generally Recognized As Safe (GRAS) determinations. She wrote a comprehensive literature review on the safety of an ingredient for the Council for Responsible Nutrition, which was provided to the FDA in June 2020.

Advisory Committees & Professional Affiliations

Current

American Botanical Council Advisory Board Member: 1999-present

American Herbal Pharmacopoeia & Therapeutic Compendium Technical Advisory Board Member: 1995-present

American Herbal Products Association Scientific Advisory Board Member: 1998-present

Previous

Agency for Healthcare Research and Quality (DHHS), Evidence-based Practice Center: Evidence Report/Technology Assessments on garlic and milk thistle: National Advisory Panel member (1999)

Herb Research Foundation: Reviewer of safety monograph: Kava (1997).

Institute of Medicine, National Academy of Sciences: Committee on a Framework for Evaluating the Safety of Dietary Supplements working group: Chaparral monograph (2002)

National Center for Complementary and Alternative Medicine, NIH: Member of special emphasis panels to evaluate SBIR/STTR applications regarding standardized botanical products and drug/herb interaction applications (2001), applications for an international complementary and alternative medicine center (2003) and other standard grant applications (2003, 2004).

National Institute of Mental Health, NIH: Member of panel assigned to review coordinating center proposals for the NIH-sponsored trial on St. John's Wort (1997).

Office of Dietary Supplements, NIH: Participant in developmental planning meetings (1996), special emphasis panel to review proposals for the first NIH-sponsored Dietary Supplements Research Centers (1999) and scientific reviewer for the Annual Bibliography of Significant Advances in Dietary Supplement Research (2002).

University of California at Los Angeles Center for Dietary Supplements Research: Botanicals (An NIH-funded Center): External Advisory Board Member (2000-2004).

United States Pharmacopoeia Committee of Experts for Dietary Supplements Information: Member (2001-2005). Vice-chair (2006-2010).

United States Pharmacopoeia Committee of Experts for Monographs - Dietary Supplements: Member (2010-2015).

World Health Organization (WHO) Guidelines on Good Herbal Processing Practices (GHPP) for Herbal Medicines: Contributor and Reviewer (2016-2017)

Speaking Engagements

“Diabetic Neuropathic Pain Decreased Upon Coadministration of CBD and PEA” invited speaker at Canna Pharma 2022. Oct. 12-13, 2022, San Diego, CA.

“Herbal Medicine” a college course lecture at the San Jose State University, yearly, Feb 2006 to present. San Jose, CA.

“Proposed Tolerable Upper Intake Level (UL) for Cannabidiol (CBD)” invited speaker at the Council for

- Responsible Nutrition (CRN)'s annual meeting, Nov.8, 2019, Carlsbad, CA
- “Clinically Tested Dietary Supplements – Selecting Clinically Tested products”, invited speaker at 12th Annual Natural Supplements: An Evidence-Based Update, Jan 15-18, 2015, San Diego, CA.
- “Botanical Safety Evaluation: The USP Process”, invited speaker at the Shanghai International Conference on Traditional Medicinal and Natural Medicine, 12-13 Oct, 2013, Shanghai, China
- “Bioequivalence of Botanical Preparations” at the USP sponsored Science & Standards Symposium on Functional Foods and Dietary Supplements-Global Opportunities and Challenges, Sept 18–20, 2012, Boston, MA.
- “Therapeutic Use of Antioxidants” a CE lecture at the 57th Annual Pharmacy Seminar at Ferris State University, Apr 6, 2010, Big Rapids, MI
- “Bioequivalence: Can a clinical study conducted on one herbal product be used to support the efficacy of another?” at the 7th Annual Oxford International Conference on the Science of Botanicals & American Society of Pharmacognosy 4th Interim Meeting, Apr 12-16, 2008, Oxford, MS
- “Herbal Remedies: a perspective for health professionals” in a continuing professional education program, “Complementary and Alternative Medicine: an update for health professionals, Univ of Montana, June 2, 2006, Missoula, MT.
- “Pharmacognosy in Clinical Trials” at the International Congress on Natural Products Research Classical Pharmacognosy Forum, Jul 31, 2004, Phoenix, Arizona.
- “Evaluating the Quality and Efficacy of Herbal Preparations” at the 12th Annual Congress on Women’s Health, June 8, 2004, Hilton Head Island, SC.
- “Pharmacognosy: Discovering the Secrets of Nature’s Chemists” a keynote address at the NY Society of Cosmetic Chemists Spring Seminal, Apr 13, 2004, Skillman, NJ.
- “Herbal Medicine” a college course lecture at the San Jose State University, February 19, 2004, San Jose, CA.
- “Herbal Remedies: a Perspective for Health Professionals” a lecture to the City of San Jose health professionals, Feb 10, 2004, San Jose, CA.
- “Herbal Remedies, a Discussion for Seniors” a lecture to City of San Jose seniors, Feb 4, 2004, San Jose, CA.
- “Clinically Efficacious Herbal Medicines” a featured speaker for the American Women in Science, Palo Alto Chapter, Dec 4, 2001, Palo Alto, CA.
- “Medicinal Plants” a college course lecture at the University of La Verne, Oct 16, 2001, La Verne, CA.
- “Herbal Product Standardization, in the crossfire” at Natural Products EXPO West, Mar 26, 2000, Anaheim, CA.
- “Models to Predict Therapeutic Benefit: Clinical, Bioassay, Chemical” in a symposium titled, “Botanicals: Let’s Talk Science #6: Emerging Methods and Technologies” at SupplySide West ’99, Nov 11, 1999, Las Vegas, NV
- "Moving Towards Harmonizing Analytical Methods" in symposium titled, "Botanicals - Let's Talk Science, Analytical Methods; Robust, Rugged and Ready" at the Natural Products EXPO West, Mar 12, 1999, Anaheim, CA.
- "Analysis of Herbal Products" at University Southern California School of Pharmacy Board of Councilor's Annual Retreat. Oct 9, 1998, Los Angeles, CA.
- "Taking a Stand on Standardization, What You Need to Know" at Natural Products EXPO East, Sep 9-13, 1998, Baltimore, MD
- "Overview of Current Pharmacological Investigations on Saw Palmetto" in American Herbal Products Symposium on Saw Palmetto, Aug 20-22, 1998, Naples, FL.
- "How to Tell Apples from Oranges, the Challenge of Herbal Identification" at Natural Products EXPO East, Sep 17-21, 1997, Baltimore, MD.

Publications

Book

Barrett, M. (2004) *The Handbook of Clinically Tested Herbal Remedies. Volumes I and II*. Haworth Press, August, 1400 pg.

Pamphlet

Barrett, M. (1998) *Reference on Evaluating Botanicals*. Council for Responsible Nutrition, Wash. D.C., 48 pg.

Book Chapters & Monograph Sections

- Barrett M (2018) *Proprietary Botanical Ingredient Scientific and Clinical monograph for BCM-95® Curcumin*. American Botanical Council, Austin, TX. Pg 1-24.
- Barrett M (2017) Red Clover Therapeutics. In, *American Herbal Pharmacopoeia and Therapeutic Compendium, Red Clover flowering tops, aerial parts and dry extracts, Trifolium pratense L., Standards of Identity, Analysis and Quality Control*. Santa Cruz, CA: AHP. pg 31-52.
- Udani J, Barrett M (2012) Carbohydrate Digestion Inhibitors: A Focus on Natural Products” In: Bagchi D, Preuss HG, eds. *Obesity: Epidemiology, Pathophysiology and Prevention, 2 nd Ed*, Boca Raton: CRC Press (Chapter 30)
- Barrett, M (2010) Bilberry. In: Coates, R.M. ed. *Encyclopedia of Dietary Supplements, 2 nd Ed*. New York: Informa Healthcare.
- Barrett M. (2010) Supplements evaluated in clinical trials: Why specific formulations matter. In: Bonakdar R, ed. *H.E.R.B.A.L. Guide*. Philadelphia, PA: Lippincott Williams & Wilkins
- Tempesta M, Barrett M. (2009) Cranberry products prevent urinary tract infections in women: clinical evidence. In: Copper R & Kronenberg F, eds. *Botanical Medicine from Bench to Bedside*. New York: Mary Ann Liebert Inc. pp 202-211.
- Barrett M. (2000) Chaparral. In, *Herbs Everyday Reference for Health Professionals*. Chandler F (Ed). Ottawa, ON. Canadian Pharmacists Association and Canadian Medical Association. pg 73-75
- Barrett M. (1999) Astragalus Therapeutics: pharmacokinetics and pharmacodynamics. In, *American Herbal Pharmacopoeia and Therapeutic Compendium, Astragalus Root, Astragalus membranaceus, Analytical, Quality Control and Therapeutic Monograph*. Santa Cruz, CA: AHP. pg 14-20.
- Barrett M (1999) Schisandra Therapeutics: pharmacokinetics and pharmacodynamics. In, *American Herbal Pharmacopoeia and Therapeutic Compendium, Schisandra Berry, Schisandra chinensis, Analytical, Quality Control and Therapeutic Monograph*. Santa Cruz, CA.: AHP. pg. 12-18.
- Barrett M. (1999) Valerian Therapeutics: pharmacokinetics and pharmacodynamics. In, *American Herbal Pharmacopoeia and Therapeutic Compendium, Valerian Root, Valeriana officinalis, Analytical, Quality Control and Therapeutic Monograph*. Santa Cruz, CA: AHP. pg. 13-17.
- Barrett M. (1999) Willow Therapeutics: pharmacokinetics and pharmacodynamics. In, *American Herbal Pharmacopoeia and Therapeutic Compendium, Willow Bark, Salix spp., Analytical, Quality Control and Therapeutic Monograph*. Santa Cruz, CA: AHP. pg 11-13.

Peer-Reviewed Scientific Publications

- Brooks J, Oketch-Rabah R, Low Dog T, Gorecki D, Barrett M, Cantilena L, Chung M, Costello R, Dwyer J, Hardy M, Jordan S, Maughan R, Marles R, Osterberg R, Rodda B, Wolfe R, Zuniga J, Valerio L Jr, Jones D, Deuster P, Giancaspro P, Sarma N (2016) Safety and performance benefits of arginine supplements for military personnel: a systematic review. *Nutrition Reviews*. 74 (11):708-721
- Wesnes KA, Barrett ML, Udani JK. (2013) An evaluation of the cognitive and mood effects of an energy shot over a 6 h period in volunteers. A randomized, double-blind, placebo controlled, cross-over study. *Appetite*. 67: 105-113

- Udani JK, Singh BB, Singh VJ, Barrett ML. (2011) Effects of Acai (*Euterpe oleracea* Mart.) berry preparation on metabolic parameters in a healthy overweight population: A pilot study. *Nutrition J.* 10:45
- Barrett ML, Udani JK . (2011) A proprietary alpha-amylase inhibitor from white bean (*Phaseolus vulgaris*): A review of clinical studies on weight loss and glycemic control. *Nutrition J.* 10:24
- Udani JK, Singh BB, Barrett ML, Singh VJ. (2010) Proprietary arabinogalactan extract increases antibody response to the pneumonia vaccine: a randomized, double-blind, placebo-controlled, pilot study in healthy volunteers. *Nutrition J.* 9:32
- Udani JK, Singh BB, Barrett ML, Singh VJ. (2009) Evaluation of Mangosteen juice blend on biomarkers of inflammation in obese subjects: a pilot, dose finding study. *Nutrition J.* 8:48
- Udani JK, Singh BB, Barrett ML, Preuss HG. (2009) Lowering the Glycemic Index of White Bread Using a White Bean Extract. *Nutrition J.* 8:52
- Koetter U, Barrett M, Lacher S, Abdelrahman A, Dolnick D. (2009) Interactions of *Magnolia* and *Ziziphus* extracts with selected central nervous system receptors. *J Ethnopharmacol.*124:421-425. Sarma DN, Barrett ML, Chavez ML, Gardiner P, Ko R, Mahady GB, Marles RJ, Pellicore LS,
- Giancaspro GI, Low Dog T. (2008) Safety of green tea extracts : a systematic review by the US Pharmacopeia. *Drug Safety.* 31(6): 469-84. Review.
- Mahady GB, Dog TL, Barrett ML, Chavez ML, Gardiner P, Ko R, Marles RJ, Pellicore LS, Giancaspro GI, Sarma DN. (2008) United States Pharmacopeia review of the black cohosh case reports of hepatotoxicity. *Menopause.* 15(4 Pt 1):628-38. Review.
- Gardiner P, Sarma DN, Low Dog T, Barrett ML, Chavez ML, Ko R, Mahady GB, Marles RJ, Pellicore LS, Giancaspro GI.(2008) The state of dietary supplement adverse event reporting in the United States. *Pharmacoepidemiol Drug Saf.* Oct;17(10):962-70. Review.
- Barrett M (2005) Can herbal products be judged equivalent? A feasibility study. Published in Bonakdar RA. Wining abstracts from the 2nd Annual Scripps Center for Integrative Medicine conference on Natural Supplements: an evidenced-based update. *J Alt Comp Med.*, 2005, 11(4): 741-747
- Livesey J, Awang DVC, Arnason JT, Letchamo W, Barrett M, Pennyroyal G. (1999) Effect of Temperature on Stability of Marker Constituents in *Echinacea purpurea* root formulations. *Phytomedicine* 6(5): 347-349
- Barrett M (1999) Regulation of Dietary Supplements. *The Integrative Pharmacy.* Aug. 8
- Barrett M. (1999) The Pharmacology of Saw Palmetto in Treatment of BPH. *Journal of the American Nutraceutical Association (JANA).* 2(3): 21-24.
- Kernan MR, Amarquaye A, Chen JL, Chan J, Sesan D, Parkinson N, Ye Z, Barrett M, Bales C, Stoddart CA, Sloan B, Blanc P, Limbach C, Mrisho S, Rozhan, E (1998). Antiviral Phenylpropanoid Glycosides from the Medicinal Plant *Markhamia lutea*. *J Nat Prod* 61: 564-570
- Ubillas R, Jolad SD, Bruening RC, Kernan MR, King SR, Sesin DF, Barrett M, Stoddart CA, Flaster T, Kuo J, Ayala F, Meza E, Castanel M, McMeekin D, Rozhon E, Tempesta MS, Barnard D,
- Huffman J, Smee D, Sidwell R, Soike K, Brazier A, Safrin S, Orlando R, Kenny PTM, Berova N, Nakanishi K (1994). SP-303, an Antiviral Oligomeric Proanthocyanidin from the Latex of *Croton lecheri* (Sangre de Drago). *Phytomedicine* 1: 77-106
- Barrett ML (1993). In-vitro studies using different anti-viral protocols to confirm the antiviral activity of SP-303 against respiratory syncytial virus. *Shaman Report* SP-303 E-060
- Barrett ML (1993). Activity of SP-303 against Human nasal wash viral isolates. *Shaman Report* SP-303 G-008
- Barrett ML, Willis AL, Vane JR (1989). Inhibition of platelet-derived mitogen release by nitric oxide (EDRF). *Agents and Actions* 27 (3-4): 488-491
- Barrett ML, Willis AL, Vane JR (1988). Anti-atherosclerotic potential of nitric oxide (EDRF) via inhibition of platelet mitogen release. *Br J Pharmacol* 95: 689P
- Desa FM, Chander CL, Corry DG, DeBrito FB, Moore AR, Barrett ML, Willoughby DA (1988). The effects of indomethacin on rat cartilage breakdown in vivo and in vitro: Potentiation with interleukin-1 in vitro. *Br J Pharmacol* 95: 678P
- O'Neil LAJ, Barrett ML, Lewis GP (1987). Extracts of feverfew inhibit mitogen-induced human peripheral blood mononuclear cell proliferation and cytokine mediated responses: a cytotoxic effect. *Br J Clin Pharmacol* 23: 81-83

- O'Neill LAJ, Barrett ML, Lewis GP (1987). Induction of cyclo-oxygenase by interleukin-1 in rheumatoid synovial cells. *Febs Lett* 212(1): 35-39
- Barrett ML, Lewis GP, O'Neill LAJ (1987). Mechanism of IL-1 induced PGE₂ formation in human synovial cells. *Br J Pharmacol* 90: 65P
- Barrett ML, Lewis GP, Ward S, Westwick J (1987). Platelet activating factor induces interleukin-1 production from human adherent macrophages. *Br J Pharmacol* 90: 113P
- Barrett ML, Lewis GP (1986). Unique properties of auranofin as a potential anti-rheumatic drug. *Agents and Actions* 19(1-2): 109-115
- Barrett ML, Scutt AM, Evans FJ (1986). Cannflavin A and B, prenylated flavones from *Cannabis sativa*. *Experientia* 42: 452-453
- Barrett ML, Lewis GP, Ward S, Westwick J (1986). Platelet activating factor modulates interleukin-2-induced proliferation of human T-lymphoblasts. *Br J Pharmacol* 89: 505P
- Lewis GP, Barrett ML (1986). Immunosuppressive actions of prostaglandins and the possible increase in chronic inflammation after cyclo-oxygenase inhibitors. *Agents and Actions* 19(1-2): 59-65
- Barrett ML, Gordon D, Lewis GP (1985). Effects of exogenous cytokines on the antiproliferation effects of inhibitors of IL-1 (MCF) release. *J Leukocyte Biol* 37(6): 684
- Barrett ML, Gordon D, Evans FJ (1985). Isolation from *Cannabis sativa* L. of Cannflavin - a novel inhibitor of prostaglandin production. *Biochem Pharmacol* 34(11): 2019-2024
- Edwards MC, Evans FJ, Barrett ML, Gordon D (1985). Structural correlations of phorbol-ester induced stimulation of PGE₂ production by human rheumatoid synovial cells, *Inflammation* 9: 33-38
- Evans AT, Formukong E, Barrett ML, Evans FJ (1985). Constituents of *Cannabis sativa* L. inhibit lipoxigenase activity. *J Pharm Pharmac* 37: 43P
- Gordon D, Barrett ML, Lewis GP (1985). Effects of exogenous cytokines on the anti-lymphoproliferation effects of auranofin and Na aurothiomalate. *Br J Rheumatol* 24 (Suppl. 1): 224-225
- Barrett ML, Gordon D, Scutt A, Evans FJ (1984). A novel flavonoid with potential anti-inflammatory activity from *Cannabis sativa* L. IUPHAR 9th International Congress of Pharmacology, 1914P, McMillan Press Ltd.
- Barrett ML, Gordon D, Scutt A, Evans FJ (1984). The structure of a novel inhibitor, isolated from *Cannabis sativa* L. of prostaglandin E₂ production by human rheumatoid synovial cells. *J Pharm Pharmac* 36:48P
- Edwards MC, Barrett ML, Gordon D, Evans FJ (1983). Stimulation of human rheumatoid synovial cells prostaglandin production by phorbol esters. *J Pharm Pharmac* 35: 14P
- Barrett ML, Gordon D, Evans FJ (1982). Inhibition of Prostaglandin E₂ production by tetrahydrocannabinol-free extract of *Cannabis sativa* L. *J Pharm Pharmac* 34:39P

Employment Previous to Consulting

Shaman Pharmaceuticals, South San Francisco, CA. 1991-94, Senior Scientist, 1993-94, Research Scientist, 1991-93

Designed, implemented and supervised the cell culture and virology laboratories which conducted *in vitro* screening assays as part of the company's ethnobotanically-driven drug discovery program. Established antiviral and cell toxicity assays that facilitated the activity-guided fractionation of plant extracts. Streamlined the screening process by initiating a system of communication between the botany, chemistry and pharmacology departments. Developed and maintained databases that facilitated management of assay results. Supervised Quality Control/Quality Assurance antiviral testing for products in clinical trials.

Planetree Health Care Resource Center, Pacific Medical Center, San Francisco, CA. Medical Researcher, 1990-91

Researched current treatments for various health issues upon individual requests from the public. Produced customized information packages including basic anatomy and physiology, research articles, literature searches on recent & experimental clinical developments and 'alternative' medical approaches.

William Harvey Research Institute, St. Bartholomew's Hosp. Med. College, London, UK. Research Scientist, 1986-89

Studied immunomodulatory effects of endothelial-derived relaxing factor (nitric oxide) in an *in vitro* model employing cultured endothelial cells and isolated platelets, mononuclear cells and granulocytes. Designed and established the cell culture laboratory for the Institute.

Department of Pharmacology, Hunterian Institute, Royal College of Surgeons, London, UK. Research Associate, 1983-86

Explored interactions between peripheral blood mononuclear cells and adherent rheumatoid synovial cells in an *in vitro* model for rheumatoid arthritis. Projects tested the effects of various stimuli, inflammatory mediators and anti-inflammatory drugs upon the production and action of cytokines and arachidonic acid metabolites.

Department of Pharmacognosy, School of Pharmacy, University of London, UK. Teaching Assistant, 1981-83

Taught undergraduates methods of extraction and chromatographic separation of biologically active natural products in B. Pharm. (Hons.) course.

Department of Pharmacognosy, School of Pharmacy, University of London, UK. Post-graduate Student, 1979-83

Thesis title: Isolation of non-cannabinoid anti-inflammatory agents from *Cannabis sativa* L. Extracted, isolated and identified biologically active flavonoids from *Cannabis sativa* L. using activity guided fractionation. Assayed extracts, fractions and pure compounds for inhibition of prostaglandin E2 release (monitored by radioimmunoassay) from cultured human rheumatoid synovial cells.

US Dept. of Agriculture Western Regional Research Center, Albany, CA. Research Technician, 1978-79

Explored chemical interactions between bacteria (*Rhizobium* sp.) and nitrogen-fixing leguminous plants.

University of California Herbarium and Jepson Herbarium, Berkeley, CA. Assistant, 1976-78

Assisted in taxonomic research, taxonomic identification of plant specimens, and maintenance of herbarium specimens.