

## EXPERT WITNESS AND CONSULTANT

**NAME:** Bob West, Ph.D., Principal

Food, Drug, Chemical Services  
7925 Meadow Rush Loop  
Sarasota, Florida 34238  
(941) 925-8958 - Tel.  
(941) 926-9615 - Fax

### PROFESSION:

Pharmacologist/Toxicologist - Biomedical, Regulatory, Pharmaceutical and Environmental Consultant to drug, device and biochemical firms with scientific, FDA/EPA regulatory and quality assurance problems.

### WORK HISTORY:

Principal, Food, Drug, Chemical Services, 1975 to present;  
Formerly Director, Scientific and Regulatory Affairs, Richardson-Merrell, 1968-1975; Vice President, Pharmacology & Toxicology, Resner-Hixson Laboratories, 1960-1968; Research Pharmacologist, American Cyanamid, 1958-1960; Research Associate, Rohm & Haas, 1956-1958.

### EXPERIENCE:

Over 35 years experience with expertise in drug and medical product development, licensing, patents and acquisitions, biomedical science, toxicology and regulatory compliance for drugs, biologics, diagnostics, biotechnology, medical devices, pesticides and chemical specialties. Expert witness in product liability, FDA, EPA, and OSHA toxic tort suits for corporations. Represents companies before these agencies for product approval requirements. Lecturer in toxicology and product safety, Fairfield University and Hartford Graduate Center. GCPs, GMPs and GLPs audits.

### ALTERNATIVE DISPUTE RESOLUTION EXPERIENCE:

Served as member of arbitration panel concerning a multi-million dollar dispute between biotech companies over licensing and distribution agreements. Has appeared before FDA/EPA government advisory panels and as an expert witness in medical/legal cases. Adequacy of efficacy and safety data for a new drug from overseas for compliance with U.S. FDA requirements and standards.

### ALTERNATIVE DISPUTE RESOLUTION TRAINING:

AAA basic and advanced arbitrator training, Washington, D.C., October, 1991

### PROFESSIONAL LICENSES:

Licensed Pharmacist, State of Vermont, 1952;  
State of New York, 1953

### PROFESSIONAL ASSOCIATIONS:

Drug Information Association (Past President); Association of Research Directors; American Society for Pharmacology and Experimental Therapeutics; Society of Toxicology; Association of University Technology Managers; Association of Pharmaceutical Scientists; Listed in *Who's Who in America* and *Who's Who in Medicine and Health Care*.

### EDUCATION:

Purdue University, Ph.D., 1956; Purdue University, M.S., 1954; Albany College of Pharmacy, Union University, B.S. 1952

**PUBLICATIONS:**

Numerous publications and presentations in pharmacology, toxicology, scientific communications, drug information and regulatory affairs.

**Legal Experience  
Research, Deposition and Testimony**

Safety of Dog Repellent to individuals inadvertently exposed, Central Illinois Power & Light, Peoria, Illinois

Adequacy of Directions for Use & Proper Dispensing of Topical 8-Methoxypsoralen - Law firms in Memphis, Tennessee; Phoenix, Arizona and Jacksonville, Florida

Safety of Topical Hydroquinones, Long Island, U.S., FDA and South African Health for International Consortium

Formaldehyde, Safety in Mobile Homes, Wisconsin State Health Hearings - SOCMA

Safety of 8-Methoxypsoralen for Psoriasis - U.S. FDA Advisory Panel, Elder/ICN

Safety of bovine bone implants for cervical discectomy, U.S. & Canadian FDA, Unilab and Washington FDA law firm

Toxicity of Antibiotic Combinations on Prolonged Use - Pennsylvania, Joseph Murray, Esq.

Drug Combinations and Alcohol on Sobriety - New Jersey

Nickel Compounds on Skin - Connecticut for AMAX

Compliance of Surgical Products with U.S. FDA Regulations - Washington and Connecticut

Qualifications, Adequacy of an Expert Witness - New Jersey

FIAU Safety and Compliance with FDA Regulations

Trimethoprim (sulfonamides) and Stevens-Johnson Syndrome

Toxicity, Hazards of Petroleum distillates and Butyl cellosolve in irritant induced asthma

Toxicity, Hazards of water treatment chemicals such as cyclohexylamine and morpholine

Addiction liability of muscle relaxants and pain killers

Drug Induced Guillain-Barre Syndrome

Dispute resolution between biotech companies over licensing and distribution agreements

Fen-Phen scientific and regulatory issues

**Bob West, Ph.D.**

**Legal Experience  
Research, Deposition and Testimony**

Safety of Dog Repellent to individuals inadvertently exposed, Central Illinois Power & Light, Peoria, Illinois - Court Appearance, 1985

Adequacy of Directions for Use & Proper Dispensing of Topical 8-Methoxypsoralen - Law firms in Memphis, Tennessee; Phoenix, Arizona and Jacksonville, Florida - Court Appearance, St. Augustine, FL, 1976

Safety of Topical Hydroquinones, Long Island, U.S., FDA and South African Health for International Consortium

Formaldehyde, Safety in Mobile Homes, Wisconsin State Health Hearings - SOCMA, 1980'S

Safety of 8-Methoxypsoralen for Psoriasis - U.S. FDA Advisory Panel, Elder/ICN - 1970'S

Safety of bovine bone implants for cervical discectomy, U.S. & Canadian FDA, Unilab and Washington FDA law firm - 1980'S

Toxicity of Antibiotic Combinations on Prolonged Use - Pennsylvania, Joseph Murray, Esq.

Compliance of Surgical Products with U.S. FDA Regulations - Washington and Connecticut

FIAU Safety and Compliance with FDA Regulations

Trimethoprim (sulfonamides) and Stevens-Johnson's Syndrome - Deposition, Arlington, VA, 1995

Toxicity, Hazards of Petroleum distillates and Butyl cellosolve in irritant induced asthma - Deposition and Court appearance, Arlington, VA, 1996

Toxicity, Hazards of water treatment chemicals such as cyclohexylamine and morpholine - Deposition Northern Virginia, 1998

Addiction liability of muscle relaxants and pain killers

Drug Induced Guillain-Barre Syndrome

Dispute resolution between biotech companies over licensing and distribution agreements - AAA Arbitration Panel, Washington, D.C., 1999-2000

Fen-Phen, compliance with FDA ADR regulatory issues - Deposition, Philadelphia, PA, 1999

Safety of specialty chemicals and personal care products upon skin contact

Hazards of multiple chemical exposures, Deposition, Sarasota, FL, 1999

Hazards of sulfuric acid exposure - Deposition, Sarasota, FL, 2001

**Bob West, Ph.D.**

**Legal Expert Experience  
By Deposition or in Trial**

**2000**

Deposition: *Guice and Puckett v. Carpenter Co.*, Circuit Court  
Chesterfield County, Virginia

*Enzon, Inc. v. Yoshitomi Pharmaceutical Industries, Ltd. and Alpha Therapeutic  
Corp.*, American Arbitration Association, Panelist, Washington, D.C.

**2001**

Deposition: *Thomas Hendrix v. Madeline Duvic, M.D., et al.*, 269<sup>th</sup> Judicial District,  
Harris County, Texas

Telephone Deposition: *Katherine Parr and Tamaira Bunge, child v. Department of  
Children & Family Services*, Orlando and Orange County, Florida

Deposition: *Crenshaw v. FritoLay*, Orange County, Florida

**2002**

Deposition: *Intrabiotics v. Iterative Clinical Technologies, Inc.*, American  
Arbitration Association in New York

Deposition: *Pat Bass v. Moltech*, Workmen's Compensation, Second Region,  
Ocala, Florida

Deposition: *Susan Nymberg v. Michael Anneken, formerly dba Medical Village  
Pharmacy, etc.*, United States District Court for the Eastern District of Kentucky,  
At Covington, Kentucky

**2003**

Deposition and trial: *Kristina Greer v. S.V.T., Inc., AKA Superior Video Tech, Inc.*,  
Circuit Court of the 9<sup>th</sup> Judicial Circuit in and for Orange County, Orlando, Florida

**2004**

Deposition: *New River Pharmaceuticals v. DSM Pharmaceuticals, Inc.*,  
U.S. District Court for Eastern District of Tennessee at Greenville, Tennessee

Deposition: *Kathleen McCormack v. Wyeth*, Superior Court of the District of  
Columbia

Page 2

Deposition: *Glenna Baker v. A.H. Robins/Wyeth*, U.S. District Court, Alexandria, Virginia

2005

Deposition: *Theresa and James Coleman v. Publix Supermarkets, Inc.*, Circuit Court of 17<sup>th</sup> Judicial Court in Broward County, Florida

Deposition: *Carolyn Kelly v. Wyeth, et al.*, Superior Court, Forsyth County, North Carolina

**Publications**

*Ammonium Lactate 12% Lotion versus a Liposome Based Moisturizing Lotion for Plantar Xerosis*, J. Am.Podiatr.Med. Assoc., Vol. 90, 502-525 (1999)