



KALA LAPIDUS PAUL, MD

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Kala Paul is a neurologist with 24 years of industry experience in product development/safety and expertise in risk communication with emphasis on health literacy. She received her MD Magna Cum Laude from the University of Texas and is a member of the FDA Risk Communication Advisory Committee.

Dr. Paul has advertising, marketing and product information development experience through heading a multidisciplinary team responsible for brand-name OTC products, including advertising and labeling development and validation for NDA and monograph products and dietary supplements. She also has had responsibility for Product Safety Surveillance for developmental and marketed products for both prescription and non-prescription products.

Over her 13-year corporate pharmaceutical career, Dr. Paul conducted multicenter trials for prescription applications in the US and Europe while at Hoffmann-LaRoche and Ciba-Geigy, and for consumer products at Whitehall-Robins Healthcare, where she was also responsible for Product Safety Surveillance. Dr. Paul was a member of the Clinical Safety Surveillance Committee for PhRMA where she headed the Emerging Practices subcommittee.

She was a faculty member for 10 years for the Drug Information Association (DIA) training course on product safety surveillance.

Dr. Paul earned a Bachelor of Science in Biology from Chatham College, Pittsburgh, Pennsylvania and a Master of Science in Marine Microbiology and Oceanography at Oregon State University, Corvallis.

PROFESSIONAL EXPERIENCE

President, The Corvallis Group, Summit, New Jersey Current

The Corvallis Group provides medical professional consulting services to the pharmaceutical industry in medical and risk communications with particular expertise in low health literacy patient communications, regulatory submissions, and pre-approval and post-marketing product safety surveillance.

Whitehall-Robins Healthcare, Madison, New Jersey

(now Wyeth Consumer)

Assistant Vice President, Medical and Clinical Affairs Jan 1997 – March 2000

Product Safety Surveillance and Product Information

Sr. Director, Clinical Research Nov 1995 - Jan 1997

Hoffmann-La Roche, Inc., Nutley, New Jersey

Director/ International Clinical Research/CNS March 1993 - Nov 1995

CIBA-Geigy Pharmaceuticals, Summit, New Jersey

CIBA-Geigy (now Novartis)

Director/ International Clinical Research/Neuropsychiatry Jan 1991 - Feb 1993

Hoffmann-La Roche, Inc., Nutley, New Jersey

Associate Director, Clinical Development/Neuropsychiatry March 1988 - Dec 1990

Assistant Director, Clinical Development/ Neuropsychiatry Nov 1986 - March 1988

**Private Practice, General Adult Neurology
Union, New Jersey**

Feb 1986 - Oct 1986

Clinical Research Associate

Department of Pathology, University of Texas Medical Branch

Nov 1976 - Aug 1977

**Clinical Chemist, Spohn Hospital
Corpus Christi, Texas**

Nov 1970 - Oct 1976

EDUCATION

Residency, Neurology

University of Texas Medical Branch, Galveston, Texas

Jan 1983 - Dec 1985

- Chief Resident, Neurology

Oct 1984 - Dec 1985

- Internship, Internal Medicine

Jan 1982 - Dec 1982

- Internship, Psychiatry

July, 1981 - Dec 1981

Doctor of Medicine, Magna Cum Laude

Aug 1977 - May 1981

Master of Science, Marine Microbiology and Oceanography (Thesis)

Oregon State University, Corvallis, Oregon

Sept 1967 - Aug 1970

Temperature and Pressure Effects on Macromolecular Synthesis in a Psychrophilic Marine Bacterium

Bachelor of Science, Biology, May 1967

Chatham College, Pittsburgh, Pennsylvania

Sept 1963 - May, 1967

TEACHING EXPERIENCE

Lecturer in Neuromuscular Diseases 1985
Department of Physical Therapy,
School of Allied Health Sciences, University of Texas Medical Branch

Lecturer in Pathology, Basic Sciences Curriculum 1979 - 1980
School of Medicine, University of Texas Medical Branch

Director, Clinical Chemistry Section Jan 1972 - Jan 1974
School of Medical Technology, Corpus Christi State University, Texas

PROFESSIONAL SOCIETIES

American Academy of Neurology
Alpha Omega Alpha Medical Honor Society (elected)
Drug Information Association
International Society for Pharmcoepidemiology
PhRMA (Pharmaceutical Research and Manufacturers Association)
Clinical Safety Surveillance Committee
Chairman: Task force on Strategic Directions, 1998-1999
Chairman: Emerging Practices subcommittee, 1998-2000

BOARD CERTIFICATION

American Board of Psychiatry and Neurology (Neurology)
Certified, November, 1989

LICENSURE

Texas
New Jersey

CERTIFICATION

Women's Business Enterprise National Council as a wholly-woman owned business, 2009

HONORS

National Student Research Forum
Urinary Nitrite and Urinary Tract Infection, May 1978
University of Texas Medical Branch
Doctor of Medicine, Magna cum Laude, 1981
Dean's List, Academic Core, 1977 to 1979
Academic Honors: Basic Science Pathology, 1979
Academic Honors: Obstetrics and Gynecology, 1980
Isabella H. Brackenridge Scholarship, May 1981
Awarded for highest academic standing and clinical excellence for a woman during medical training
Member: Special Task Force of the Dean of Medicine for evaluation of medical student competence, 1985
Member: Board of Trustees, Chatham College, Alumna Trustee, 1994-1997
Member: Board of Overseers, Department of Microbiology, Oregon State University, 1998 - 2000
Member: FDA Risk Communication Advisory Committee, Term Nov 2009-2013

PHARMACEUTICAL PRESENTATIONS

Basics Concepts in Drug Development: from molecule to medicine
Congressional Health Aides, Washington, DC, 1995

Understanding the Process of Prescription Pharmaceutical Development
National Organization of Women Legislators, Sante Fe, NM, Oct 1995

Safety, tolerability and pharmacokinetics of the N-methyl-D-aspartate antagonist Ro-01-6794/706 in patients with acute ischemic stroke. Marburg International Conference on Cerebral Circulation, Marburg, Germany, July 1994

Safety Considerations in Pharmaceutical Development, Prescription to Over-the Counter
Drug Information Association: Course in Product Safety Surveillance, October 1998; March 1999, March 2000

The Role of Drug Safety in Premarketing Drug Development, British Institute for Regulatory Affairs, MSc Course, Univ of Wales, Cardiff, Wales, October, 1999

Legal Ramifications for Labeling and Pharmacovigilance, Center for Business Intelligence 2nd Annual Conference on Global Pharmacovigilance, Philadelphia, April 2000

Pharmaceutical Risk Assessment: Evaluating new approaches. DIA Annual Meeting, San Diego, June 2000. Session chairperson.

An Industry Perspective: Incorporating Learnings from Patients in Risk Communication. Literacy, Language and Culture: Missing Links in Our Goal to Reduce Health Disparities, Philadelphia, April 2005

An Industry Perspective: Incorporating Learnings from Patients in Risk Communication. DIA Annual Meeting, Washington, DC. June 2005

Health Literacy: On the Road to Improving Consumer Medical Information. DIA Web Seminar, May 24, 2006.

Learnings from Consumer Research in Risk Communication. FDA Public Hearing on Use of Medication Guides to Distribute Drug Risk Information to Patients – June 12-13, 2007.

PUBLICATIONS

Paul KL, et al. Effects of hydrostatic pressure and temperature on the uptake and respiration of amino acids by a facultatively psychrophilic marine bacterium. J Bacteriol. 1971 Nov; 108(2):835-43.

James GP, et al. Urinary nitrite and urinary-tract infection. Am J Clin Pathol. 1978 Oct; 70(4):671-8.

Bee DE, et al. Hemoglobinuria and hematuria: accuracy and precision of laboratory diagnosis. Clin Chem. 1979, Oct; 25(10):1696-9.

Safety, tolerability and pharmacokinetics of the N-methyl-D-aspartate antagonist Ro-01-6794/706 in patients with acute ischemic stroke. The Dextrorphan Study Group and Hoffmann-La Roche. Ann N Y Acad Sci. 1995 Sep 15;765:249-61; discussion 298.

Safety, tolerability, and pharmacokinetics of the N-methyl-D-aspartate antagonist dextrorphan in patients with acute stroke. Dextrorphan Study Group. Stroke. 1995 Feb; 26(2):254-8.

Ewell A, Toth F, Wolfe B, et al. Thirteen year secular trend Analysis of Manufacturer-Received Advil® Spontaneous Adverse Experience Reports. Pharmacoepi Drug Safety. 1998;7: Supp 2(054) p101.

Languages: Speak and read:
French, Spanish, German

Citizenhip: United States