

*William Y. W. Au, M.D.  
February 6, 2015*

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**WORK EXPERIENCE**

**BUSINESS/INDUSTRY**

**Norwich Clinical Research Associates Ltd.**

Medical Director, Clinical Pharmacology and Clinical Research (1994-present)

Consultations in general clinical pharmacology, in clinical development of NCE, and in calcium and metabolic bone disease, especially osteoporosis clinical trials, and for infectious disease and urinary incontinence Phase 1 and 2a clinical trials. Medical monitoring, regulatory assessments of client's products for NCE, medical devices, OTC agents. Head of medical affairs group providing all trial services for clients ranging from protocol development to clinical operations to data management to final report completed. Training of CRA and staff on clinical aspects and clinical pharmacology of IP's of specific clinical trials conducted by NCRA. Lead clinical team in completion of 5 FDA IND files submissions for clients; and, in the past 4 years completed three (3) Phase 2 multicenter GCP clinical trials and filed with FDA the final medical-statistical study reports, and for the clients clinical pharmacology efficacy and safety assessment of trial results for their use for further development of respective products.

**Norwich Eaton Pharmaceuticals/Procter & Gamble Pharmaceuticals (1984-1994)**

Medical Director, Clinical Pharmacology and Experimental Therapeutics  
Medical Director, Metabolic Bone Disease and Osteoporosis Therapeutics  
Director for Clinical Trials and Medical Monitor:

Strategic planning for clinical trial program for new drugs from preclinical development through Phase I through Phase III human clinical research. Developed and wrote protocols, directed, and monitored pivotal Phase III trials for intermittent, cyclical etidronate treatment regimen for postmenopausal osteoporosis; presentations of data to European Regulatory Authorities for successful registration and marketing launch. Designed and developed clinical trials for prevention and treatment of glucocorticoid-induced osteoporosis with etidronate or with risedronate. Prepared and wrote clinical sections for IND for new chemical entities ( risedronate) and for NDA submissions. Final reports of clinical trials and studies: analysis and interpretation of trial results and clinical assessment and meaning of statistical reports for large multicenter Didrocal osteoporosis trials; for studies on treatment of hypercalcemia with etidronate IV; for dose-ranging trials; for pharmacokinetic studies of etidronate in patients with chronic renal diseases, and in elderly women. In addition served as Medical Director/Monitor for initial clinical progression of drugs under preclinical development in the following therapeutic areas: asthma, bronchitis, cardiotoxic, dysrhythmia, non-narcotic analgesic, antiarthritic, endocrine and metabolic oral peptides (calcitonin, insulin) formulations, cholesterol metabolism.

## ACADEMIC

The University of Rochester School of Medicine and Dentistry , Associate Professor of Pharmacology and of Medicine, (1963-1976)  
The University of Arkansas for Medical Sciences, Professor of Medicine and of Pharmacology, Head, Clinical Pharmacology Unit, (1976-1984)

SUNY Upstate Medical University, Professor of Medicine (Adjunct), Syracuse (1995 - 2007)  
SUNY Binghamton University, Decker School of Nursing, Professor of Nursing (Adjunct), (200-2004)

Teaching: At Rochester and Little Rock, basic courses in general pharmacology; clinical pharmacology; attending in general internal medical services; attending in clinical pharmacology and rational therapeutics; attending in endocrinology and metabolic diseases (diabetes), subspecialty in mineral disorders and metabolic bone diseases; courses in introduction to medicine and physical diagnosis. Directed and conducted workshops on clinical pharmacology and rational therapy for the aged patients for Veterans Administration Regional Educational Centers. Developed curriculum in Clinical Pharmacology SUNY HSC, Syracuse. Lecturer in Graduate Nursing School course on Regulated Clinical Research Trials.

Patient Care: Conducted general medicine clinic at Rochester General Hospital and at VA Medical Center, Little Rock; also conducted specialty clinic and consultative service for metabolic bone diseases at Rochester General Hospital and Strong Memorial Hospital, and at University Hospital, Little Rock; consultative services in clinical pharmacological, therapeutics, and toxicological problems at all hospitals. Service in diabetes clinic and in general endocrine and metabolic disease consultation in VA Hospital and University Hospital, Little Rock.

Research: Regulation of parathyroid gland metabolism *in vitro* parathyroid glands by organ cultures; effect of chronic renal disease on parathyroid and vitamin D metabolism; influence of aging on pharmacokinetic and metabolism of drugs (theophylline, etidronate disodium in human studies); clinical trials of agents for treatment of osteoporosis, Paget's disease, hypercalcemia, metastatic bone disease, and hypertension.

## PROFESSIONAL AND ACADEMIC POSITIONS HELD

- 2000- 2004 **SUNY Binghamton University, Decker School of Nursing Graduate School, Binghamton, NY**  
Adjunct Professor of Nursing (Clinical Research)
- 1996 - Present **SUNY Upstate Medical Center, Syracuse, N.Y.**  
Professor of Medicine (Clinical Pharmacology) Volunteer Faculty
- 1994 - Present **Norwich Clinical Research Associates Ltd**  
Medical Director, Clinical Pharmacology and Clinical Research
- 1984 - 1994 **Procter & Gamble Pharmaceuticals Inc.**  
(formerly Norwich Eaton Pharmaceuticals, Norwich, N.Y.)  
Medical Director, Regulatory and Clinical Affairs  
Section Head, Clinical Pharmacology and Experimental Bone Therapeutics

Director of Clinical Pharmacology, Medical Affairs

- 1976 - 1984 **University of Arkansas for Medical Sciences, Little Rock, AR**  
Professor of Medicine and Pharmacology; and, Chief, Clinical Pharmacology Division, College of Medicine (tenured)
- 1970 - 1976 **The University of Rochester School of Medicine and Dentistry, Rochester, NY**  
Associate Professor of Pharmacology and of Medicine (tenured)
- 1969 - 1970 **St. Mary's Hospital Medical School, London, UK**  
Visiting Professor in Biochemistry (Drug Metabolism)
- 1963 - 1970 **The University of Rochester School of Medicine and Dentistry, Rochester, NY**  
Assistant Professor of Pharmacology and of Medicine

### **PROFESSIONAL EDUCATION/TRAINING**

Boston University College of Liberal Arts  
A.B. with distinction in biology, 1951

Boston University School of Medicine,  
M.D., magna cum laude, 1955

State University of New York Health Science Center, Syracuse:  
Intern in Medicine, 7/15/55 - 6/30/57  
Assistant Resident in Medicine, 7/1/55 - 6/30/57  
Resident in Medicine, 7/1/57 - 6/30/57  
Research Fellow in Medicine, 7/1/58 - 6/30/59  
in Renal and Electrolyte Metabolic Disorders, - L.G. Raisz, M.D., Director

National Institutes of Health, National Heart Institute, Bethesda, MD;  
Postdoctoral Research Fellow in Endocrinology, 9/1/61 - 6/30/63,  
in Laboratory on Endocrinology and Metabolic Diseases - F.C. Bartter, M.D., Director

University of Rochester Medical Center, Rochester, NY;  
Trainee in Clinical Pharmacology, 7/1/63 - 6/30/65,  
in Clinical Pharmacology Unit and Laboratory on Calcium Regulation and Metabolic Bone Diseases, L.G. Raisz, M.D., Head and Director

### **MEDICAL LICENCES**

New York: #079390  
Arkansas: #C-5317 (retired)

### **HOSPITAL APPOINTMENTS HELD**

Veterans Administration Hospital, Little Rock, AR  
Physician and Chief, Clinical Pharmacology Section  
University Hospital, UAMS, Little Rock, AR

Attending Physician  
Rochester General Hospital, Rochester, NY  
Consultant in Medicine; Attending Physician  
Strong Memorial Hospital, Rochester, NY  
Senior Associate Physician

### **PROFESSIONAL SOCIETIES**

American Society for Pharmacology and Experimental Therapeutics  
American Society for Clinical Pharmacology and Therapeutics  
American College of Clinical Pharmacology  
Endocrine Society  
American Society for Bone and Mineral Research

### **MILITARY SERVICE**

Captain, USAF (MC), Internist, USAF Hospital, Maxwell AFB, Alabama Jul 19, 1959-July 19, 1961.

### **RESEARCH INTERESTS**

Bone and Mineral Metabolism

Regulation of parathyroid hormone synthesis and secretion by humoral and by pharmacological agents (corticosteroids, vitamin D metabolites, thiazide diuretics).

Clinical pharmacology and therapeutics

Phase I and Phase II Dose Ranging, Pharmacodynamic, and Pharmacokinetic Human Trials.

Endocrine and Metabolic Disease, especially in Osteoporosis clinical trials, treatment of Paget's disease, hypercalcemia, and metastatic bone diseases.

Geriatric clinical pharmacology

Effect of aging on drug metabolism and on therapeutic responses/drug interactions.

### **LECTURES, PRESENTATIONS, AND COMMUNITY SERVICES**

Have presented 51 formal lectures, seminars, and medical staff rounds to health professional groups (other than medical students). A list of titles is available on request. Additional presentations, not listed, were to clinicians, investigators, or research groups on the design and results of pivotal clinical trials with intermittent, cyclical etidronate regimen for treatment of osteoporosis (postmenopausal and corticosteroid-induced); on the management of hypercalcemia; as well as on other topics on pharmaceutical drug development.

1998-2008. Honored by Annual William Au, M.D. Lecture in Clinical Pharmacology, Department of Medicine, SUNY Upstate Medical University, Syracuse.

Chair, Adult Immunization Task Force, Chenango Health Network, Chenango County, NY (1998-2001)

Member, Advisory Committee, Area Agency for Aging, Chenango County, NY (1995-present)

Member, Advisory Committee, NY State Office for Aging (term 2004-2009)

**BIBLIOGRAPHY**

I have published 41 papers related to my research work; and 18 published for presentation at research meetings. Bibliography is available on request. In addition I have completed over 20 formal reports on clinical trial results, FDA, IND, NDA, and PLA submissions at Procter & Gamble Pharmaceuticals and for NCRA clients. These are not listed due to confidential proprietary considerations.  
Completed 4 IND final clinical-statistical GCP study reports for submission to FDA.