

FOUNDER & CEO - Barry Mangum, PharmD, FCP

SUMMARY

35 years in Pharmacotherapy and Pediatric clinical research and education.

BA in Chemistry from UNC-Wilmington, NC; BS and Doctorate of Pharmacy from Medical University of South Carolina-Charleston.

AREAS OF EXPERTISE

Pediatric Clinical Research, Pediatric Clinical Trials Implementation (all phases), Development Plans, Clinical Trials Staff Management, Contract Management, Regulatory Issues Resolution, Research Infrastructure Planning (from funding to implementation), Raising Capital, Consultative and Scientific Advisory Services, Education/Teaching, Customer Service.

PROFESSIONAL EXPERIENCE: ACADEMIC

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| <u>Associate Professor, Clinical Pharmacology, Duke University Medical School</u> | (2003-2015) |
| <u>Director, Clinical Pharmacology, Duke Clinical Research Unit</u> | (2008 - 2015) |
| <u>Assistant Professor, Pediatrics, Duke University Medical School</u> | (2003-Present) |
| <u>Director, Neonatal/Pediatric Pharmacotherapy</u>
<u>Wake Area Health Education Center (AHEC), Raleigh NC</u> | (1989-1998) |
| <u>Clinical Associate Professor, UNC-Chapel Hill</u>
<u>Schools of Medicine and Pharmacy, Department of Pediatrics/Pharmacotherapy</u> | (1989-1998) |
| <u>Director of Pharmacy Clinical Services, Wake AHEC, Raleigh NC</u> | (1986-1989) |
| <u>Clinical Assistant Professor, UNC-Chapel Hill</u>
<u>Schools of Medicine and Pharmacy, Department of Pediatrics/Pharmacotherapy</u> | (1983-1999) |

PROFESSIONAL EXPERIENCE: CORPORATE

Paidion Research, Inc.

As CEO and Co-Founder, responsible for overall management and success, vision and mission. Implement clinical trials in all phases of pediatric drug development. Raise capital.

Executive Director, Neonatal Programs: Inhibitex, Inc., Alpharetta, GA

Responsible for overall leadership, management and direction of INH-A21 neonatal programs in neonatal sepsis. Implemented clinical trials in all phases of drug development for INH-A21. Managed contracts and regulatory issues associated with the first neonatal programs.

Senior Director, Pediatric Clinical Development Services: Quintiles, Inc., RTP, NC

Responsible for overall leadership, management and direction of group. Developed strategies for success by creating sound pediatric clinical development plans for large pharmaceutical clients. Provided consultative and scientific advisory services related to neonatal and pediatric project plans. Delivered excellent customer service to enhance business relationships and revenues.

Associate Director: WakeMed Clinical Research Institute, Raleigh, NC

Responsible for overall management of clinical staff implementing Phase II through IV clinical trials. Designed total infrastructure for institute, from proposal funding to implementation. Served as sub-investigator on more than 50 clinical trials.

CONSULTANT APPOINTMENTS: 1987 - Present

United States Food and Drug Administration, Glaxo Wellcome, Bayer, Wyeth, King Pharmaceuticals, PBM, Inhibitex, Shire Pharmaceuticals, Bristol-Myers Squibb, Solvay, Alza, Novartis, Reliant Pharmaceuticals, Merck Pharmaceuticals, Medex, Ross Laboratories, Abbott Laboratories, Baxter Healthcare, Alpha Therapeutics, IEP Group, Inc., Ohmeda, Air Shields, SpaceLabs Medical, Corometrics, TAP, AstraZeneca, First Horizons Pharma, FSC Labs, Pfizer, Ovation Pharma, Avaxia Biologics, Kirin Pharma, GW Pharmaceuticals, Alios Pharmaceuticals and AbbVie.

CURRENT RESEARCH PROJECTS

NEMO- EU-FP-7 Novel Treatment for Post Asphyxia Seizure Disorder in the Neonatal Patient, Study Number 241479, Total funding \$15,000,000 over five years. 2009- present.

NIH-NIDA- Novel Ondansetron Formulation for Combination Treatment of Psychostimulant Abuse, Grant Number: 1RC2DA028905-01, total funding \$2,200,000 over two years. 2009-present.

NIH Clinical and Translational Science Award (CTSA), supported 65% effort for clinical pharmacology research unit. \$53,000,000 total award, 2006-present.

NIH-NICHD- Pediatric Pharmacology Research Unit, co-awarded with University of North Carolina at Chapel Hill, total funding \$350,000 annually. 2003-present

Mangum, O.B., Young, T.E. A Multicenter Program to Evaluate EMLA Cream for Skin Anesthesia in Children Undergoing Selected Invasive Procedures, Protocol Number:92-EML-14, NDA Number: 19-941, Astra Pharmaceuticals Funding thru Premier Hospital Alliance, Inc., total funding \$1200.

Young, T.E. Mangum, O.B. A Randomized Control Trial of Surfactant Administration in Neonates Using a Modified Endotracheal Tube. Funded by Ross Labs and Burroughs Wellcome, total funded \$40,000.

Mangum, O.B., Young, T.E. In Vitro Compatibility of Albuterol and Dexamethasone in a Nebulizable Solution. Funded by Glaxo, Inc. Total funding \$8,000.

PUBLICATIONS: Refereed

Pressler R, Boylan GB, Blennow M, Chiron C, Cross HJ, de Vries LS, Hallberg B, Hellstrom-Westas L, Jullien V, Livingstone V, **Mangum B**, Marlow N, Murphy B, Murray D, Pons G, Rennie J, Swarte R, Toet M, Vanhatalo S, Zohar S. Evaluation of bumetanide as second line treatment for neonatal seizures in a phase I/II dose finding and feasibility trial (NEMO). In press Lancet 2014.

Fowler JC, Szabo ST, Patkar A, **Mangum B**, Beyer WB, Yang LY, Chow SC, Burnett B, Froeliger B, Lee TH. Development and Pharmacokinetic Characterization of Delayed, Pulsatile-release Ondansetron Formulation. In press, 2014.

Marier JF, **Mangum B**, Reid E, Barrett JS. A Modeling and Simulation Framework to Support Global Regulatory Strategies for Pediatric Drug Development Programs. Therapeutic Innovations and Regulatory Sciences, Sept, 2013.

Young TE, **Mangum OB**. Neofax - A Manual of Drugs Used in Neonatal Care. Ed 21. Raleigh, North Carolina: Acorn Publishing, USA, 2010.

Baker-Smith CM, Benjamin DK Jr, Grabowski HG, Reid ED, **Mangum B**, Goldsmith JV, Murphy MD, Edwards R, Eisenstein EL, Sun J, Califf RM, Li JS. The economic returns of pediatric clinical trials of antihypertensive drugs. Am Heart J. 2008;156:682-8.

Cohen-Wolkowicz M, Smith PB, **Mangum B**, Steinbach WJ, Alexander BD, Cotten CM, Clark RH, Walsh TJ, Benjamin DK Jr. Neonatal Candida meningitis: significance of cerebrospinal fluid parameters and blood cultures. J Perinatol. 2007;27:97-100.

Li, J.S., Eisenstein, E.L., Grabowski, K.G., Reid, E.D., **Mangum. O.B.**, et al. Economic Return of Clinical Trials Performed Under the Pediatric Exclusivity Program, JAMA; 2007;297:480-488.

DeVeugh-Geiss J, March J, Shapiro M, Andreason PJ, Emslie G, Ford LM, Greenhill L, Murphy D, Prentice E, Roberts R, Silva S, Swanson JM, van Zwieten-Boot B, Vitiello B, Wagner KD, **Mangum B**. Child and adolescent psycho-pharmacology in the new millennium: a workshop for academia, industry, and government. J Am Acad Child Adolesc Psychiatry. 2006; 45:261-70.

PUBLICATIONS: Non-Refereed

- ***Mangum, B.** The Clinical Use of Lung Surfactant Preparations: Practical Considerations. Pharmacy Times. July 1992; 61.
- ***Mangum, B.** The Use of Lung Surfactant Preparations: Practical Considerations. Wake Medical News. 1992;18:1.
- ***Mangum, O.B.,** Brown, K. Caffeine Used for Neonatal Apnea. Wake Medical Pharmacy News. May 1990.
- *Young, T.E. **Mangum, O.B.** Drugs Used in Breastfeeding. Evansville, Indiana: Mead Johnson Laboratories; 1989.
- ***Mangum, O.B.** Theophylline - A Second Look. Wake Medical Pharmacy News. May 1989.

PUBLICATIONS: Books

Young, T.E., **Mangum, O.B.** *Neofax - A Manual of Drugs Used in Neonatal Care*. Ed 19. Raleigh, North Carolina: Acorn Publishing, USA, 2008. (Publication years: 1987-2010)

*Co-authored, copyrighted, marketed and published *NeoFax: A Manual of Drugs Used in Neonatal Care*; the leading manual for dosing neonatal medications in the United States, published in English, Chinese, German, Portuguese, Russian, Polish, and Spanish.

*Co-authored, copyrighted and published *NeoFax-em*, *NeoFax-Rx*, and *NeoFax-pn*, an electronic family of neonatal drug dosing and nutrition software (2001,02,03,04,05,06,07)

*Co-authored *Neofax Palm* and *Pocket PC* (2001,02,03,04,05,06,07)

PUBLICATIONS: Selected Abstracts

***Mangum, O.B.**, Imaging Biomarkers. Presented at DIA 2012 Conference, Philadelphia, USA: June 2012.

* **Mangum, O.B.**, Risk Assessment Process for Pediatric Protocol Development. Presented at DIA 2011 Conference, Chicago, USA: June 2011.

*Houff, J.E., **Mangum, O.B.** and Glover, M.L. Continuous Nebulization of Albuterol in Pediatrics. ASHP Annual Meeting, Washington, D.C. 6/92.

*Young, T.E. and **Mangum, O.B.** Surfactant Administration Using a Modified Endotracheal Tube. Poster Hot Topics 12/91-A Special Ross Conference, Washington, D.C. 12/91.

*Glover, M.L. and **Mangum, O.B.** Nutritional Cost Containment Proposal for a Neonatal Intensive-Care Unit. Poster Presentation ASHP Clinical Midyear Meeting, New Orleans, Louisiana; 12/91.

*Houff, J.E. and **Mangum, O.B.** Standardization of Syringe Concentrations for Drugs Used in the Neonatal Intensive-Care Unit. Poster Presentation ASHP Clinical Midyear Meeting, New Orleans, Louisiana; 12/91.

*Glover, M., **Mangum, O.B.**, Speight, KP. Implementation of a Unit Dose Syringe System in a Neonatal Intensive Care Unit. Poster Presentation ASHP Annual Meeting, San Diego, California; 6/90.

*Young, T.E., **Mangum, O.B.** Theophylline Protein Binding in the Neonate. Pediatric Research 1988; 23: A3886.

*McCue, J., Kavenaugh, R., Gal, P., **Mangum, O.B.**, Bear, W., Roberts, B. In Vivo Inactivation of Tobramycin by Beta-Lactam Antibiotics. Presented at the ICAAC Lecture Oct, 1983.

*Cooper, J.F., **Mangum, O.B.**, and Thomas, R.W. Inference of Heparin Locks in In Vivo Labeling of Red Blood Cells. Presented at the 21st Southeastern Chapter of the Society of Nuclear Medicine. Oct. 1980.

PUBLICATIONS: Editorials and Position and Background Papers

Reviewer, Therapeutic Innovations and Regulatory Sciences, 2014

Editorial Board of Contemporary Clinical Trials, 2014

Reviewer, European Commission FP-7, 2007

Reviewer, Journal of Perinatology, 2005-2015

Reviewer, Pediatric Pharmacology Research Units, NICHD, 2005, 06, 07

Chinese Journal of Pediatric Emergency Medicine 2004, 2005

Series editor, **Cardiofax**, Blackwell Science, 2001

Series editor, **Dermafax**, Blackwell Science, 2001

Series editor, **Neurofax**, Blackwell Science, 2001

PROFESSIONAL AWARDS

*Annual Service Award, DIA	2014
*World Health Organization (WHO) Expert Advisory Panel on Drug Evaluation	2010
*Nominated Distinguished Faculty Award, Medical University of South Carolina	2009
*Fellow in Clinical Pharmacology, American College of Clinical Pharmacology	2008
*Excellence in Teaching Award, Wake Medical Center/Wake AHEC (for 13 years of service to Pediatrics)	1998

MEMBERSHIPS

American Society of Clinical Pharmacology and Therapeutics (ASCPT)

Governmental Affairs Committee

Editorial Board

Scientific Program Committee

Finance Committee

American College of Clinical Pharmacology (ACCP)

Editorial Board

Fellow

American Academy of Pediatrics (AAP)

Perinatal Society

Drug Information Associates (DIA)

SIAC Clinical Pharmacology

Program Committee

RTP-(DMDG) Executive Committee

Pediatric Infectious Disease Society

American Society of Health-Systems Pharmacists (ASHP)

American College of Clinical Pharmacy (ACCP)

North Carolina Society of Health-Systems Pharmacists (NCSHP)

Rho Chi Society

Marcus Evans 8th, 9th, Annual Pediatric Clinical Trials Conference, Chairperson

Hawaii Society for Respiratory Care, Faculty