2025 CURRICULUM VITAE

Harold E. Bays MD, MFOMA, FTOS, FACC, FNLA, FASPC

Medical Director / President

Louisville Metabolic and Atherosclerosis Research Center Inc. (L-MARC Research Center)

Clinical Associate Professor

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RESEARCH EXPERIENCE

Dr. Harold Bays has served as an Investigator for over <u>700</u> Phase I - IV clinical trials for treatments for obesity, diabetes mellitus, dyslipidemia, hypertension, osteoporosis, and other metabolic and hormonal disorders. Dr. Bays has served as Medical Director of L-MARC Research Center since 1989 and has served as President of L-MARC Research Center since its independent incorporation in 1998.

EMPLOYMENT HISTORY

1973-1974: Busboy, Dishwasher

1974-1976: Cook

1976-1978: Janitor

1978-1980: Clerk/Cashier

1980-1990: Musician

1988-1998: National Touring Professional Stand-Up Comedian

1989-1993: Endocrine Associates PSC (Private Practice)

1993-2008: Louisville Endocrinology PSC (Private Practice)

1989-Present: Medical Director L-MARC Research Center (Research Appointment)

2017-Present: Medical Director "Your Body Goal" Center for Body Composition, Body Weight, and Body Metabolism

UNIVERSITY AFFILIATION

2021 - Present: Clinical Associate Professor - University of Louisville School of Medicine

MOONLIGHTING

VA Hospital Emergency Dept.

Hardin County Memorial ER Lebanon Emergency Dept.

Flemingsburg Emergency Dept.

Hardinsburg Emergency Dept.

Jackson Emergency Dept.

Radcliff Emergency Dept.

EDUCATION

1973-76: High School Degree = Bowling Green High School

1976-80: Bachelor of Science = Western Kentucky University

1980-84: Medical Degree = University of Louisville School of Medicine

1984-87: Internship/Residency Internal Medicine = University of Louisville School of Medicine

1987-89: Fellowship in Endocrinology and Metabolism = the University of Louisville School of

Medicine

CERTIFICATION

Board Certification: Internal Medicine (1987)

Board Certification: Endocrinology and Metabolism (1989) Diplomate of the American Board of Clinical Lipidology (2011) Diplomate of the American Board of Obesity Medicine (2013)

MEDICAL LICENSE

Kentucky

PROFESSIONAL MEMBERSHIPS, CHAIRMANSHIPS, BOARD OF DIRECTORS, AND TASK FORCE SERVICE

Professional Society Officer Position

• Chief Science Officer – Obesity Medicine Association (2021 – present)

Professional Membership Fellow

- Master Fellow of the Obesity Medicine Association (MFOMA)
- Fellow of The Obesity Society (FTOS)
- Fellow of the American College of Cardiology (FACC)
- Fellow of the American Society of Preventive Cardiology (FASPC)
- Fellow of the National Lipid Association (FNLA)

Scientific Memberships

- Member: Obesity Medicine Association (OMA)
- Member: The Obesity Society (TOS)
- Member: World Obesity Federation (WOF)
- Member: National Lipid Association (NLA)
- Member: American Society of Preventive Cardiology (ASPC)
- Member: The Endocrine Society
- Member: American Association of Clinical Endocrinologists (AACE)
- Member: American College of Cardiology (ACC)
- Member: American Diabetes Association (ADA) Recognized Provider in the ADA's National Committee for Quality Assurance (NCQA) from 1998 – 2010
- Member: American Medical Association (AMA)

Chairmanships

- Chairman/Co-Chairman: The Obesity Medicine Association Obesity Algorithm (2016 2021)
- Chairman: The Obesity Society Membership Committee (2012-2014)
- Chairman: National Lipid Association Adiposity and Dyslipidemia Consensus Conference 2012
- Chairman: American Association of Clinical Endocrinologist Adipose Tissue Pathophysiology State of the Science Conference - 2010
- Chairman: American Association of Clinical Endocrinologist Pathogenic Adipose Tissue Task Force (2006-2010)
- Chairman: "Study to Help Improve Early evaluation and management of risk factors Leading to Diabetes" (SHIELD) (2003 2011)
- Chairman: Endocrine Subcommittee for Alternative Health Delivery Systems (1996-7)

Scientific Board of Directors

- Board of Trustees: Obesity Medicine Association (2018 Present)
- Board of Directors: American Society of Preventive Cardiology (2019 2022)
- Board of Directors: National Lipid Association (2013 2019)
- Board of Directors: American Board of Clinical Lipidology (2017 2019)
- Board of Directors: South East Lipid Association (2009 2017)
- Board of Directors: American Association of Clinical Endocrinologists (2010)

Scientific Committees, Officer, and Task Force

- Executive Officer: Obesity Medicine Association President (starting from April 2025)
- Executive Officer: Obesity Medicine Association President Elect (2024 2025)
- Executive Officer: Obesity Medicine Association Vice President (2022 2024)
- Executive Officer: Obesity Medicine Association Secretary/Treasurer (2021 2022)
- Executive Officer: National Lipid Association Secretary/Treasurer (2015 2017)
- President: SouthEast Lipid Association (2015 2016)
- Committee Member: The Obesity Society Education Committee (2013 2015)
- The Obesity Medicine Association Presenter for the American Board of Obesity Medicine (ABOM) Review Course (2024 Present)
- The Obesity Society American Board of Obesity Medicine Review Course Presenter (2013 2023)
- Contributing author of the National Lipid Association Annual Summary of Clinical Lipidology 2015 2016
- Contributing author of the National Lipid Association Recommendations for Patient-Centered Management of Dyslipidemia Part 1 2014
- Contributor to the National Lipid Association Recommendations for Patient-Centered Management of Dyslipidemia Part 2 2015
- Contributing author to the Obesity Medicine Association Obesity Algorithm 2013 2021

Scientific Editor

- Editor in Chief: Obesity Pillars (official journal of the Obesity Medicine Association): 2022 present
- Editor: Obesity Medicine Association (OMA) Self-Assessment Program (SAP) 2020
- Associate Editor: Journal of Preventive Cardiology (2019 2021)
- Guest Editor and lead author of the National Lipid Association Annual Summary of Clinical Lipidology 2016
- Guest Editor and lead author of the National Lipid Association Annual Summary of Clinical Lipidology 2015
- Associate Editor: Journal of Clinical Lipidology (2013 2017)
- Scientific Writer: Obesity Medicine Association Obesity Algorithm (2013 2021)

AWARDS:

2019: Obesity Medicine Association "Dr. Peter G. Linder Award"

2016: Obesity Medicine Association "Obesity Medicine Clinician of the Year"

2015: National Lipid Association "President's Service Award"

2014: Obesity Medicine Association "Committee Leadership Award"

VOLUNTEER EXPERIENCE

1990 – 2005: "Recognized with Honor" for past participation as a physician volunteer in the Jefferson Co. Medical Society's Outreach Program for the Homeless "The Healing Place"

MEDICAL PRESENTATIONS

Since 1989, Dr. Harold Bays has given numerous medical presentations at major scientific meetings, educational programs to physician groups, and has been a featured presenter at numerous symposia.

BRIEF BIOGRAPHY - MEDICAL / RESEARCH

Publications

Dr. Bays has served as a Principal Investigator for over <u>700</u> clinical trials including investigational pharmacotherapies for dyslipidemia, obesity, diabetes mellitus, hypertension, osteoporosis, osteoarthritis, and other metabolic disorders. He has written or served as a contributing author to over <u>350</u> Pub-Med searchable, peer review scientific manuscripts and book chapters, and authored/presented <u>hundreds</u> scientific abstracts.

Dr. Bays has published in journals such as the New England Journal of Medicine, Archives of Internal Medicine, Journal of the American Medical Association, Obesity Pillars, Nature Medicine, Obesity/Obesity Research, Journal of Clinical Endocrinology and Metabolism, Cell Metabolism, Diabetes Care, Journal of American College of Cardiology, Circulation, Atherosclerosis, Metabolism, American Journal of Preventive Cardiology, European Journal of Preventive Cardiology, The American Journal of Medicine, Journal of Clinical Lipidology, Medical Clinics of North America, Lipids in Health & Disease, Current Atherosclerosis Reports, Drug Development & Research, Expert Opinion on Investigational Drugs, Journal of Cardiovascular Therapy, Endocrine Practice, Diabetes Obesity and Metabolism, Expert Opinion on Pharmacotherapy, Progress in Drug Research, Journal of Clinical Pharmacology, Mayo Clinic Proceedings, Current Opinion in Lipidology, Nutrition Metabolism, Nutrition Journal, Journal of Cardiovascular Pharmacology, American Journal of Cardiology, Drug Safety, Clinical Therapeutics, Journal of Cardiovascular Drugs, American Journal of Therapeutics, Clinical Therapeutics, Metabolic Syndrome and Related Disorders, Preventive Cardiology, Expert Review

of Cardiovascular Therapy, US Endocrine Diseases, Current Medical Research and Opinion, Current Treatment Options in Cardiovascular Medicine, Evidence-based Cardiovascular Medicine, European Heart Journal, Therapy, Clinical Cardiology, Future Cardiology, Future Lipidology, International Journal of Clinical Practice, Drugs in Research and Development, Coronary Artery Disease, European Journal of Neurology, Hospital Pharmacy Europe, Nature Clinical Practice Cardiovascular Medicine, BMC Public Health, Management Strategies in Diabetes, Vascular Health and Risk Management, Nutrition Metabolism & Cardiovascular Disease, Archives of Gynecology and Obstetrics, Today in Cardiology, Managed Care Supplement, California Journal of Health Promotion, Journal of Women's Health, and has been a scientific contributor to www.lipidsonline.org.

Expert Reviewer

Dr. Bays has served as an expert manuscript reviewer for over $\underline{60}$ scientific medical journals including: New England Journal of Medicine, Journal of the American Medical Association (JAMA), The Lancet, Archives of Internal Medicine, Obesity Pillars, Obesity Research/Obesity, International Journal of Obesity, Annals of Internal Medicine, Journal of the American College of Cardiology (JACC), Diabetes, Diabetes Care, Journal of Clinical Endocrinology and Metabolism (JCEM), American Journal of Preventive Cardiology, The American Journal of Medicine (AJM), American Journal of Cardiology (AJC), Endocrine Practice, The American Heart Journal, European Heart Journal, The Journal of Internal Medicine, Regulatory Peptides, Methods and Findings in Experimental and Clinical Pharmacology, Diabetic Medicine, Opinion in Molecular Therapeutics, Mayo Clinic Proceedings, Environmental Science & Technology, Journal of Diabetes, Archives of Medical Research, Physician and Sports Medicine, Diabetes Obesity and Metabolism, Current Pharmaceutical Design, Annuals of Nutrition and Metabolism, Biomarkers in Medicine, Current Medical Literature - Cardiology, Biochemical Pharmacology, Vascular Health and Risk Management, Drug Discovery Today, Investigational Drug Database, Trends in Pharmacological Sciences, Expert Opinion on Biologic Therapy, Drugs, Journal of the American College of Nutrition, Journal of Clinical Lipidology, American Journal of Cardiovascular Drugs, Expert Opinion on Pharmacotherapy, Expert Opinion on Investigational Drugs, International Journal of Clinical Practice, Pharmacological Research, Expert Opinion on Drug Safety, Life Sciences, Drug News and Perspectives, Consultant, Future Lipidology, Nature Clinical Practice Cardiovascular Medicine, Expert Opinion on Therapeutic Targets, Expert Opinion on Emerging Drugs, Public Library of Science, Metabolic Syndrome and Obesity: Targets and Therapy, Treatments in Endocrinology, Indian Journal of Medical Research, Journal of Clinical Outcomes Management, Advances in Preventive Medicine, Vascular Health and Risk Management, Aging Health, Agro Food Industry Hi-Tech, Clinical Pharmacology in Drug Development, Pharmacy and Therapeutics, Metabolic Syndrome and Related Disorders, Mount Sinai Journal of Medicine, Diabetes/Metabolism Research and Reviews, Cardiovascular Drugs and Therapy, Combination Products in Therapy and Journal of Cardiovascular Drugs.

Consultant/Advisor

Integral to his duties as Medical Director of a metabolic research facility, Dr. Bays serves as a national and international advisor and consultant to pharmaceutical companies and investors in

drug development. His expertise involves the practical aspects of protocol design, for the purpose of obtaining scientifically valid results, clinically meaningful results, and fulfillment of regulatory requirements. As importantly, because of his vast experience as a clinical trials Investigator and advisor to numerous prior protocols, Dr. Bays often provides unique insights into practical study design issues that affect recruitment and retention, which are critical for timely clinical trial startup, timely completion, and clinical validity when interpreting study results.

Dr. Bays has served as the sole Investigator of single-site "proof of concept" and other studies conducted at L-MARC Research Center wherein timeliness, quality, and cost-effectiveness are premium considerations. At the end of studies, Dr. Bays is often asked to conduct the tedious, yet thorough review of Clinical Study Reports, and assist with scientific abstract submission and eventual publication of study results.

In addition to his research relationships with larger pharmaceutical companies, Dr. Bays has also advised smaller pharmaceutical companies in their development programs and has spoken on their behalf to investors or others involved in potential collaborations and partnerships. He also advises larger capitalized pharmaceutical companies in helping determine the relative advantages and disadvantages of potential acquisitions or other collaborations with smaller, upstart drug companies developing promising novel therapeutic agents.

Regulatory and Patent Assistance

Dr. Bays has aided in various regulatory matters, such as input in pharmaceutical company interactions with the FDA Center for Drug Evaluation and Research (CDER). Specifically, Dr. Bays has helped provide input towards effective and successful Special Protocol Assessment (SPA) submissions, with a focus on crafting the most appropriate regulatory questions regarding the protocol, protocol design (including proposed size), study conduct, study goals, and/or data analysis for the proposed investigation. Dr. Bays has also represented pharmaceutical companies in direct discussions with regulatory agencies regarding issues that naturally arise during the submission and development process. Such representation includes being a presenter regarding metabolic pharmaceuticals at FDA Endocrine and Metabolism Drug Advisory Committee (EMDAC) meetings in Washington DC (White Oak / Silver Spring MD).

Finally, beyond regulatory matters regarding the FDA, Dr. Bays has also served as an advisor and expert in working with the US Patent Office, as it applies to pharmaceutical declaration statements, and responses to federal patent examiners.

Academic Presentations

Dr. Bays has presented at international symposia, university conferences (e.g. Grand Rounds), and invited educational presentations, including Continuing Educational Education (CME) programs.