Clinical Utility of Treating Patients with Compounded “Bioidentical Hormone Replacement Therapy”

Committee

Donald R. Mattison

Chair

Donald R. Mattison, M.D., was appointed Chief Medical Officer and Senior Vice President of Risk Sciences International in 2012. Dr. Mattison also serves as Associate Director of the McLaughlin Centre for Population Health Risk Assessment at the University of Ottawa. He has held academic, clinical and research appointments, including; Senior Advisor to the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, Medical Director of the March of Dimes; Dean of the Graduate School of Public Health at the University of Pittsburgh, Professor of Obstetrics and Gynecology and Interdisciplinary Toxicology at the University of Arkansas for Medical Sciences, and Director of Human Risk Assessment at the FDA National Center for Toxicological Research. Dr. Mattison earned a BA (Chemistry and Mathematics) from Augsburg College in Minneapolis, MN, an MS (Chemistry) from the Massachusetts Institute of Technology, Cambridge, MA and a MD from the College of Physicians and Surgeons, Columbia University, New York, NY. His clinical training in Obstetrics and Gynecology was at the Sloane Hospital for Women in the Columbia Presbyterian Medical Center in New York. His training in Pharmacology and Toxicology was at the National Institutes of Health, Bethesda, MD. In 1997, he was elected a Fellow of the American Association for the Advancement of Science, in 1999, a Fellow of the New York Academy of Medicine, in 2000 a member of the Institute of Medicine, in 2005 Distinguished Alumni of Augsburg College and in 2009 a Fellow of the Royal Society of Medicine.

Ruth M. Parker

Vice Chair

Ruth Parker, M.D., attended Davidson College and received her medical training at the University of North Carolina, Chapel Hill. She completed her residency and chief residency at the Strong Memorial Hospital in Rochester, New York, and her fellowship as a Robert Wood Johnson Foundation Clinical Scholar at the University of Pennsylvania. She holds Board Certification in both Internal Medicine and Pediatrics. Dr. Parker is currently Professor of Medicine and Pediatrics at the Emory University School of Medicine and holds a secondary appointment at the Emory University School of Public Health in the Division of Epidemiology. Dr. Parker's primary research interests and activities have been in the area of medical education and health services of underserved populations. She has been actively involved in medical education and faculty development since joining the medical school faculty. For over two decades, Dr. Parker has focused extensively on healthcare issues of underserved populations, particularly health literacy. She was a principal investigator in the Robert Wood Johnson Literacy in Health Study and helped create a widely used measurement tool to quantify patients' ability to read and understand health information (TOFHLA, the test of functional health literacy in adults). She has authored numerous papers on health literacy, and co-edited the complete bibliography of medicine on health literacy for the National Library of Medicine. She co-authored the most widely used definition of health literacy, which was used in Healthy People 2010 and 2020 and is currently used by the National Academies and by the NIH. Dr. Parker currently serves as consultant and advisor to numerous federal agencies, professional societies, and members of industry on their initiatives related to health literacy.

Lesley H. Curtis

Member

Lesley H. Curtis, Ph.D., is a health services researcher who oversees a portfolio of projects that use observational data to address questions related to clinical and comparative effectiveness, pharmacoepidemiology, health care delivery, and epidemiological trends across a broad array of clinical conditions and clinical care settings. An expert in the use of Medicare claims data for health services and clinical outcomes research, she has led the linkage of Medicare claims with several large clinical registries and epidemiological cohort studies including the Framingham Heart Study and the Cardiovascular Health Study. Dr Curtis is Professor and Chair of Population Health Sciences and Interim Director of the Duke Clinical Research Institute at Duke University. She leads the Distributed Research Network Operations Center for PCORI's National Clinical Research Network (PCORnet), working with health systems and patient networks to develop a harmonized data infrastructure for robust observational and interventional research. Areas of expertise: Health Services Research and Health Policy.

Susan S. Ellenberg

Member

Susan S. Ellenberg, Ph.D., Professor of Biostatistics, Medical Ethics and Health Policy at the University of Pennsylvania Perelman School of Medicine. Prior to joining Penn in 2004, Dr. Ellenberg held leadership positions at the NIH and the FDA. Her research interests have focused on issues in the design, conduct and analysis of clinical trials, and on assessment of medical product safety. Particular areas of interest include efficient trial designs, interim monitoring and the operation of data monitoring committees, evaluation of surrogate endpoints, ethical issues in clinical research, and special issues in trials of cancer and AIDS therapies, and of vaccines. She is an associate editor of Clinical Trials and of the Journal of the National Cancer Institute. Dr. Ellenberg is a fellow of the American Statistical Association, the American Association for the Advancement of Science and the Society for Clinical Trials, and an elected member of the International Statistical Institute. She has served as president of the Society for Clinical Trials and the Eastern North American Region of the International Biometric Society, and has chaired the Statistics Section of the AAAS and the Board of Trustees for the National Institute of Statistical Sciences. The second edition of her book on clinical trials data monitoring committees, co-authored with Drs. Thomas Fleming (University of Washington) and David DeMets (University of Wisconsin), will appear in 2019.

Jennifer Fishman

Member

Jennifer Fishman, Ph.D., is a sociologist of science, technology, and medicine. She uses empirical qualitative methods to describe and analyze the emergence of new medical knowledge and technologies, from the early stages of development to their integration into clinical practice and dissemination to clinicians and patients. Often referred to as “empirical ethics,” she analyzes the oft unexamined and presumptive ethics and values within new scientific enterprises and how these impact research trajectories, technological diffusion and commercialization, and ultimately patients/consumers. She has studied new pharmaceutical drug development and advertising, anti-aging science and medicine, direct-to-consumer genetic risk susceptibility testing, end-of-life medical decisions, prenatal genetic carrier testing panels, and the promise of personalized genomic medicine. Dr. Fishman received her Ph.D. in Sociology at the University of California, San Francisco, and her BA at the University of California, Berkeley.

Adel H. Karara

Member

Adel H. Karara, Ph.D., FCP is Professor of Pharmaceutical Sciences, teaches in the areas of pharmaceutics, biopharmaceutics and pharmacokinetics. Prior to joining UMES, he held senior positions in the pharmaceutical industry. His research had been primarily in the female health care area working on the pharmacokinetics/dynamics of combination hormone treatments. As Senior Clinical Pharmacologist at Roche, he had the responsibility for guiding the selection of early drug discovery compounds, due diligence projects and design of clinical pharmacology development programs for several metabolic drug candidates. Before joining Roche, he was Director at Berlex where he provided NDA support for Yasmin®, ClimaraPro® Menostar® and Angeliq®. At Novartis, he provided support for Starlix®, Lescol® and Neoral®. Dr. Karara was a tenured faculty at University of Louisiana where he mentored 3 PhD & 2 MS students and won the researcher of the year award. Dr. Karara is a Charter member of American Association of Pharmaceutical Scientists (AAPS), participated in teaching short courses and served on abstract screening committees. Dr. Karara was elected to serve as the Chair of the Clinical Pharmacology and Translational Medicine Section of AAPS. He has 39 peer reviewed publications and was invited speaker at several clinical pharmacology forums. He served on Pharmaceutical Research and Manufacturers of America, Clinical Pharmacology Technical Group where he led the exploratory Investigational New Drug (IND) survey initiative. Dr. Karara currently serves on the FDA Pharmaceutical Science and Clinical Pharmacology Advisory Committee for oncology drugs (ODAC). Dr. Karara is a fellow of American College of Clinical Pharmacology and serves on the editorial board of the Journal of Clinical Pharmacology.

Aaron S. Kesselheim

Member

Aaron Kesselheim, M.D., J.D., M.P.H., is a Professor of Medicine at Harvard Medical School (HMS) and a faculty member in the Division of Pharmacoepidemiology and Pharmacoeconomics in the Department of Medicine at Brigham and Women’s Hospital (BWH). He is Board Certified in Internal Medicine, and serves as a primary care physician at the Phyllis Jen Center for Primary Care at BWH. Within the Division, Dr. Kesselheim created and leads the Program On Regulation, Therapeutics, And Law (PORTAL), an interdisciplinary research core focusing on intersections among prescription drugs and medical devices, patient health outcomes, and regulatory practices and the law. His research has concentrated on the interaction of law and public health related to drug discovery, testing, and regulatory approval, using a combination of quantitative and qualitative research tools and normative study. Author of over 350 publications in the peer-reviewed medical and health policy literatures, Dr. Kesselheim was recently recognized as the second most-cited health law scholar in Web of Science from 2013-2017. He has testified before Congress a half-dozen times on pharmaceutical policy, medical device regulation, generic drugs, and modernizing clinical trials, is a member of the FDA Peripheral and Central Nervous System Advisory Committee, and served on a National Academies of Science, Engineering and Medicine consensus committee on addressing the opioid epidemic. Aaron is a core faculty member at the HMS Center for Bioethics, where he co-teaches a course on health policy, law, and bioethics and organizes a popular monthly policy and ethics seminar series. Aaron also serves as the Irving S. Ribicoff Visiting Associate Professor of Law at Yale Law School, where he teaches a yearly course on Food and Drug Administration Law. He serves on the Perspectives Advisory Board of the New England Journal of Medicine and is the editor-in-chief of the Journal of Law, Medicine, and Ethics.

Robert MacArthur

Member

Robert MacArthur, Pharm.D., M.S., earned his Pharm.D. at St. John's University, in New York, and MS in Biostatistics at Columbia University, also in New York. For over 30 years he has been continuously engaged in the fields of commercial drug development, clinical research, and research pharmacy. His experience includes large pharma (Sandoz, Novartis), small/mid pharma (Systems Medicines, CTI, Aeson Therapeutics, Cancer Prevention Pharmaceuticals, multiple others), and academia, along with running his own companies. On behalf of these sponsors he has worked with and presented to FDA, EMA, NIH, NCI, patient groups, CROs, CDMOs, and others, always with the objective of moving a promising medication along the critical path towards regulatory approval. Over this time he has contributed to the development of many hundreds of human medicines, leading to multiple drug approvals. At AmPharmStatistics.com, (APS) Robert has the good fortune to work with highly experienced and talented statisticians. At APS, he is able to apply his knowledge and skills to pharmaceutical statistics and reporting for regulatory submissions, and to support clinical trial groups, for large and small pharma companies.

Jose E. Manautou

Member

José Manautou, Ph.D., is a Professor of Toxicology and Interim Head of the Department of Pharmaceutical Sciences at the University of Connecticut. He was selected to serve on the National Advisory Environmental Health Sciences Council (NAEHSC), part of the National Institute of Environmental Health Sciences (NIEHS) in 2017. He has also served on the Board of Scientific Counselors within NIEHS. He is a world-renowned expert in acetaminophen hepatoxicity. Dr. Manautou received his undergraduate degree in pharmacy from the University of Puerto Rico and his Ph.D. in pharmacology and toxicology from Purdue University. He came to UConn as a post-doctoral researcher in 1992, working with pioneering toxicologist Professor Emeritus Steven Cohen. He was named a tenure track assistant professor in Toxicology in 1995, and received tenure and promotion to associate professor in 2001.

Nancy K. Reame

Member

Nancy King Reame, Ph.D., MSN is the Mary Lindsay Professor Emerita of Health Promotion and Risk Reduction in the School of Nursing at Columbia University in New York City. From 2005-2015, she directed the Pilot Studies Resource of the Irving Institute for Clinical and Translational Research in the College of Physicians and Surgeons and was the Director of the PhD program in Nursing. From 1980-2005, she held faculty posts at the University of Michigan in the School of Nursing and the Department of Obstetrics-Gynecology in the School of Medicine. Dr. Reame’s research is focused on the impact of reproductive neuroendocrinology on women’s health across the lifespan. Current studies include the role of menopause on cognition and HIV symptoms, and the impact of endometriosis on menstrual cycle phenotypes. A member of the Institute of Medicine, Dr. Reame is a women's health advocate, having served on the advisory committee to the NIH Women's Health Initiative, and as advisor for many years to the Boston Women's Health Book Collective for the iconic book, “Our Bodies, Ourselves.” A past member of the Board of Trustees for the North American Menopause Society, she is certified as a menopause clinician. Nancy received her undergraduate degree in nursing from Michigan State University, a Master’s degree as a clinical nurse specialist from Wayne State University College of Nursing, and a PhD in physiology from Wayne State University School of Medicine, with postdoctoral training in reproductive endocrinology at the University Of Michigan School Of Medicine.

David R. Rubinow

Member

David R. Rubinow, M.D., is the Meymandi Professor and Chair, Department of Psychiatry, at the University of North Carolina-Chapel Hill, School of Medicine; prior to being recruited to the University of North Carolina, he was Clinical Director of the National Institute of Mental Health (NIMH) and Chief of the Behavioral Endocrinology Branch of NIMH. His research interests focus on neurobehavioral effects of gonadal steroids and how genetic variation contributes to differential behavioral response to changes in steroid signaling. Research methods used include administration of hormone super agonists and receptor blockers to manipulate the menstrual cycle and identify the central effects of gonadal steroids in isolation. These studies have demonstrated that, unlike mood disorders accompanying endocrinopathies, reproductive endocrine-related mood disorders represent abnormal responses to normal hormonal signals. Current NIH funded studies include investigations of continuous oral contraceptive administration in menstrual cycle-related mood disorders, estradiol effects on cardiovascular risk and mood dysregulation during the perimenopause, and biomarkers of postpartum depression. Additionally, the UNC Women’s Mood Disorders Program, which he directs, has the first and only NIH training fellowship in Women’s Mood Disorders. On the basis of his research, he was inducted into the Institute of Medicine of the National Academies in 2012.

Rulla Tamimi

Member

Rulla Tamimi, Sc.D., aims to better understand breast cancer risk by incorporating biospecimens and molecular tools in epidemiologic studies. She is an Associate Professor of Medicine at Harvard Medical School. She and her team have led research on breast cancer, including work on lifestyle risk factors, biomarkers, genetics and gene expression. She studies intermediate markers of breast cancer risk including benign breast disease and mammographic density as an approach to better understand early life influences on breast cancer risk. Working with computer scientists, she and her group are identifying additional mammographic imaging features that predict risk of breast cancer. By leveraging molecular tools and intermediate markers of risk, Dr. Tamimi hopes to shed new light on our understanding of risk factors of breast cancer with the goal of identifying strategies for breast cancer prevention and improved risk assessment. She received her M.S. and ScD.D. from the Harvard School of Public Health.