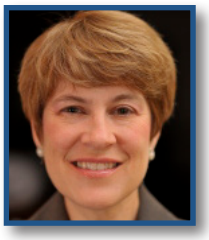
National Institute of Biomedical Imaging and Bioengineering

Workshop on
Clinical Translation of Molecular Imaging Probes and Technology

August 2, 2013
Lister Hill Auditorium
National Institutes of Health
Bethesda, Maryland

Speakers List

Dr. Lynne Johnson is Professor of Medicine at Columbia University, New York. Dr. Johnson graduated from Columbia College of Physicians and Surgeons, where she did her residency in Internal Medicine and Cardiology. She has served on the faculty at Columbia University, U of Alabama at Birmingham and Brown University and currently holds the title of Professor of Clinical Medicine at Columbia University. She is considered a pioneer in the field of Nuclear Cardiology and contributed to the development of perfusion imaging tracers in current clinical use as well as imaging technology, and image processing. She teaches Cardiology and Radiology trainees in clinical nuclear imaging and has mentored clinical and research scientists in their early careers. She has had a longstanding interest in cardiovascular molecular imaging-using animal models to investigate applications for novel radionuclide probes targeting sites in vasculature and myocardium that are important in clinical disease. She began by imaging myocardial necrosis in acute myocardial infarction and cardiac transplant rejection with radiolabeled monoclonal antibodies targeting myosin and continued by investigating probes targeting myocardial hypoxia, apoptosis, and angiogenesis in hibernating myocardium using both small and large animal models. The rapidly growing field of molecular biology has elucidated the pathobiology of atherosclerosis from early plaque development, growth and vulnerability to rupture. This body of information has provided investigators with potential targets for in-vivo imaging and Dr. Johnson has pursued the goal of imaging plaque vulnerability in both small and large animals by targeting apoptosis, metalloproteinase expression, angiogenesis, and expression of receptor for advanced glycation endproducts (RAGE) using SPECT/CT and more recently optical imaging. She has published over 80 papers that cover the spectrum from clinical to more basic translational work.



Dr. Maren Laughlin is currently the Senior Advisor for Integrative Metabolism in the Division of Diabetes and Endocrinology and Metabolic Diseases at the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). Dr. Laughlin was educated at Oberlin College and Yale University in Chemistry, and was a Senior Staff Fellow at the Laboratory of Cardiac Energetics at the National Heart, Lung and Blood Institute and an assistant professor in the Department of Surgery at George Washington University Medical Center before joining NIDDK. She manages a portfolio of grants and projects in the physiology of insulin resistance and in functional and molecular imaging in metabolic disease. She is also the scientific officer for the Mouse Metabolic Phenotyping Centers, a group of six Centers that provide in-depth metabolic phenotyping of mouse models of diabetes and obesity on a fee for service basis. Dr. Laughlin is interested in the application of non-invasive imaging approaches to understand the basis of human metabolic diseases.

Dr. Kirk Frey is currently the David E. Kuhl Professor of Nuclear Medicine in Radiology and Professor of Neurology at The University of Michigan. Dr. Frey is Chief of the Division of Nuclear Medicine and Molecular Imaging, Director of the Center for Positron Tomography, and Co-Director of the Movement Disorders Clinic in Neurology. He serves currently on the Board of Directors of the American Board of Nuclear Medicine and on the Board of Directors of the American Board of Medical Specialties. He has reported more than 170 peer-reviewed manuscripts and has held NIH grant support continuously for the past 25 years. He is the recipient of the Marc Tetalman Memorial Award and the Kuhl-Lassen Award from the Society of Nuclear Medicine and is a Distinguished Investigator in Academy of Radiology Research. His research interests focus on molecular imaging of neurodegenerative diseases, including Parkinson disease, Alzheimer disease and related disorders.

Dr. Joshua M. Farber is Chief of the Inflammation Biology Section at the National Institute of Allergy and Infectious Diseases (NIAID). Dr. Farber obtained his M.D. from Johns Hopkins University, where he did additional clinical training in internal medicine and infectious diseases. Dr. Farber's postdoctoral training in bench research was both at NIH and at Johns Hopkins. Dr. Farber joined the NIAID Laboratory of Clinical Investigation in 1993, became a senior investigator in 2000, and moved to the Laboratory of Molecular Immunology at its inception in 2004. Dr. Farber's research has focused on the biology of lymphocyte-active chemokines and their receptors. A recent project in the laboratory has involved imaging the chemokine receptor CXCR4 using PET.

Dr. Thomas J. Meade received a B.S. in Chemistry, his M.A. in Biochemistry and his Ph.D. in Inorganic Chemistry. After completing a NIH postdoctoral fellowship at Harvard Medical School, he was a postdoctoral fellow at the California Institute of Technology in the laboratory of Professor Harry B. Gray. In 1991 he joined the Division of Biology and the Beckman Institute at Caltech. In 2003, he moved to Northwestern University where he is currently the Eileen Foell Chair in Cancer Research and Professor of Chemistry, Biochemistry and Molecular & Cell Biology, Neurobiology & Physiology, and Radiology, as well as the Director of the Center for Advanced Molecular Imaging (CAMI). Professor Meade's research focuses on bioinorganic coordination chemistry and its application in research that include biological molecular imaging, electron transfer processes and the development of electronic biosensors for the detection of DNA and proteins. He has received numerous awards and founded three biotech companies, Clinical Micro Sensors, PreDx and Ohmx which are developing hand-held devices for protein and DNA detection and bioactivated MR contrast agents for in vivo imaging of cancer.

Dr. Stanislav Emelianov is a Cockrell Family Professor of Biomedical Engineering at the University of Texas at Austin, and a Professor of Imaging Physics at the University of Texas M.D. Anderson Cancer Center in Houston. Since his arrival to Texas in 2002, Dr. Emelianov has formed the Ultrasound Imaging and Therapeutics Research Laboratory – home to research projects in medical imaging, therapeutics and nanobiotechnology. Furthermore, Dr. Emelianov is co-Director of the University of Texas Center for Emerging Imaging Technologies focused on the translation of instrumentation and nanobiotechnology for clinical applications. Dr. Emelianov's research interests are in the areas of intelligent imaging and patient-specific therapeutics including cancer imaging and diagnosis, the detection and treatment of atherosclerosis,

the development of imaging and therapeutic nanoagents, guided drug delivery and controlled release, as well as cellular, molecular, functional, and multi-modal imaging, and image-guided therapy. Dr. Emelianov is an author of more than 300 archival publications. Throughout his career, he has mentored and served on dissertation committees of more than 60 graduate students. Finally, Dr. Emelianov is active in several professional organizations including the Institute of Electrical and Electronic Engineers (IEEE), the Optical Society of America (OSA), and the Society of Photo-Optical Instrumentation Engineers (SPIE).

Dr. Chester Mathis has a long standing interest in applying synthetic radiochemistry techniques to develop PET radiopharmaceuticals to study brain function in vivo. Over the past 25 years, he has focused primarily on the development of radiotracers to image the serotonin and dopamine neuroreceptor systems, as well as agents to evaluate other aspects of normal and abnormal function in the central nervous system using PET imaging techniques. Approximately 10 years ago, Dr. Mathis joined efforts with Dr. William E. Klunk of the Department of Psychiatry at the University of Pittsburgh to devise a PET radiotracer capable of imaging amyloid. This work led to the development of a new class of highly successful radiopharmaceutical agents, among which is Pittsburgh Compound-B, to non-invasively assess amyloid load in the living human brain using PET imaging methodology. As the Director of the University of Pittsburgh PET Facility, Dr. Mathis works closely with more than 25 University of Pittsburgh investigators from 8 departments on more than 70 PET research imaging protocols in animals and human subjects. These projects include neuroscience, diabetes, and oncology research studies using more than 40 different PET radiotracers to image a variety of biological processes in animals and human subjects.

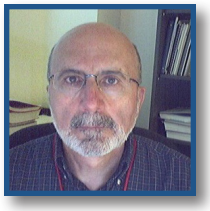
Dr. Martin G. Pomper attended college at the University of Illinois at Urbana-Champaign, majoring in biochemistry and chemistry. Also at Illinois, in the context of the Medical Scholars Program, he earned M.D. and Ph.D. degrees, the latter in organic chemistry. All of his postgraduate medical training was undertaken at the Johns Hopkins University School of Medicine, which included an internship in medicine (Osler Service), residencies in radiology and nuclear medicine, and a neuroradiology fellowship. He is currently William R. Brody Professor of Radiology. His research interests involve molecular imaging, particularly of central nervous system processes and cancer. Dr. Pomper is also the director of the Small Animal Imaging Resource Program (SAIRP) at Johns Hopkins and Deputy Director of the In Vivo Cellular and Molecular Imaging Center (ICMIC). Specific research projects in central nervous system imaging include (a) using magnetic resonance spectroscopy (MRS) to uncover brain metabolic correlates of AIDS dementia, (b) using positron emission tomography (PET) to study molecular (neurotransmitter) and cellular abnormalities in patients with AIDS dementia, and (c) the development of new radiopharmaceuticals for imaging nicotinic and glutamatergic neurotransmission. In oncology, advanced magnetic resonance imaging (MRI) techniques, such as sodium imaging, diffusion tensor imaging, and MRS are being used to study brain tumors. In addition, PET agents are being pursued to study prostate cancer, angiogenesis and to study the pharmacokinetics of chemotherapeutic agents in vivo. From a clinical standpoint, his interests lie in central nervous system vasculitis and brain tumor imaging, serving as a member of the Johns Hopkins Vasculitis Center and of a consortium to develop New Approaches to Brain Tumor Therapy (NABTT). In collaboration with the Department of Neurosurgery, he is heading up a new initiative to develop an imaging center dedicated to the characterization of brain tumors.

Dr. Paula M. Jacobs is Associate Director, Cancer Imaging Program in the Division of Cancer Treatment and Diagnosis at the National Cancer Institute. She came to work at the NCI after 30 years in the pharmaceutical and medical device industries where she was a key developer of ultrasmall superparamagnetic iron oxide drugs as magnetic resonance imaging agents and iron replacement therapeutics. Her efforts for NCI have been focused on lowering the scientific, logistical, and regulatory barriers to investigational use of PET radiopharmaceuticals for therapeutic drug development by facilitating access to IND filings and by research to develop labeled drugs for clinical and preclinical use. Another effort is focused on wide-ranging aspects of standardization and quantitative imaging techniques and a third focus is on genome-imaging correlations. Dr. Jacobs serves on three NCI Experimental Therapeutics (NExT) committees to review and manage the projects chosen for development. She directs a radiochemistry facility in Frederick that prepares preclinical and early clinical radiopharmaceuticals in support of therapeutic drug development. Dr. Jacobs received her undergraduate degree in chemistry at the Massachusetts Institute of Technology and graduate degrees at Tufts University and Northeastern University. Her post-doctoral training was at Northeastern University, Massachusetts Institute of Technology, and Peter Bent Brigham Hospital/Harvard Medical School. Her industrial experience began at Clinical Assays, a division of Baxter Travenol that manufactured in vitro radioimmunoassays, where she was responsible for process improvements in radioactive tracer synthesis, technical product maintenance, product and process improvements, and manufacturing of all reagents used in the company's products. At Seragen, a small biotechnology firm, she was General Manager, with P&L responsibility for a division that developed, manufactured, and marketed prostaglandin, leukotriene, and small protein immunoassays. Subsequently she joined Advanced Magnetics as Vice President, Development, where she was responsible for development of iron oxide magnetic contrast agents from laboratory synthesis through IND submissions, including designing pharmacology, toxicology, and clinical studies. She served as international liaison for technology transfer to licensees and worked with independent physicians in the U.S. and abroad to develop physician IND trials in MR imaging and collaborated with academic researchers in a variety of preclinical investigations. She has published papers in the areas of organic chemistry, inorganic chemistry, magnetic resonance imaging, neuro-oncology, and nephrology.

Dr. Kevin Maresca is a member of the Pfizer PTx Precision Medicine team, as Associate Director of PET and Molecular Imaging, he leads PET studies for various research units within Pfizer, including both preclinical and clinical studies. Kevin joined Pfizer from Molecular Insights Pharmaceuticals (Cambridge, MA) where he worked for 14 years, having most recently served as Director of Radiochemistry and Production. He is a multi-faceted chemist with more than 15 years of pharmaceutical drug discovery and development in the area of targeted radiolabeled small molecules and peptide-based injectable drug product candidates. He possesses extensive experience preparing regulatory filings in support of INDs. Overall, he has been significantly involved with the advancement of 8 radiolabeled small molecules into clinical trials. He has an excellent track record of patents (>10), publications (>30), and grant authorship, including the development and optimization of a lyophilized sterile kit formulation for the drug product 99mTc-MIP-1404, a potent prostate specific membrane antigen (PSMA) inhibitor for the diagnostic imaging of metastatic prostate cancer. Kevin received his PhD in Chemistry from Syracuse University, and was a Postdoctoral Fellow at Harvard Medical School, Brigham and Woman's Hospital. During these years, Kevin's research focused on the complexation chemistry of Rhenium and the development of novel metal chelators for use in the development of diagnostic imaging agents.

Dr. Gilles Tamagnan directs Laboratory Research and Development at Molecular Neuroimaging, Inc. (MNI). He received his Ph.D. in Medicinal Chemistry at the University Joseph Fourier in Grenoble, France in 1993. After a post-doctoral fellowship spent on the crystallization of proteins, Dr. Tamagnan completed a second postdoctoral fellowship at RBI in Boston, Massachusetts. His research subject was to develop new ligands for the diagnosis of Parkinson disease using compounds labeled with radioactive atoms. He joined the NeuroImaging program at Yale University in June 1997 to work on the development of new radioligands to study neurodegenerative diseases and came to MNI in 2003. Dr. Tamagnan has been the recipient of numerous grants and is the co-inventor of ligands used for the diagnosis of Parkinson disease. In 2003, he joined MNI as Laboratory Research and Development Director.

Dr. Daniel B. Vigneron is a Professor in the Department of Radiology and Biomedical Imaging and a Professor in the Department of Bioengineering and Therapeutic Sciences at the University of California, San Francisco. He is also Director of the Advanced Imaging Technologies Resource Group, Director of the Hyperpolarized MRI Technology Resource Center, and Associate Director of the Surbeck Laboratory for Advanced Imaging at UCSF. Dr. Vigneron's professional activities focus on the advancement of biomedical MRI research. Dr. Vigneron obtained his BA in Chemistry from Wesleyan University in Middletown, Connecticut in 1983, and he received his PhD in Pharmaceutical Chemistry from UCSF in 1988 for his graduate work on applying new MRI techniques for characterizing disease and therapy response. In 1990, he completed a postdoctoral fellowship from the Fox Chase Cancer Center in Philadelphia and in 1991 he completed a postdoctoral scholarship from UCSF. Dr. Vigneron's research is focused on the development of metabolic magnetic resonance imaging techniques for research and clinical assessments of human diseases. His initial focus was on developing 3D MR spectroscopic imaging for the non-invasive assessment of brain tumor metabolism. Another major research interest of Dr. Vigneron's is the characterization of prostate cancer using novel MR metabolic imaging techniques. Developing specialized acquisitions techniques for prostate cancer MRSI has been a major project for Dr. Vigneron and his group. Dr. Vigneron leads the technical development aspects of hyperpolarized carbon-13 MR program at UCSF and is the Principal Investigator of three projects focused on new metabolic MRI techniques. He has published over 200 articles, over 10 book chapters and over 450 abstracts related to his research.



Dr. Libero (Louis) Marzella is the Acting Director in the Division of Medical Imaging Products (DMIP) of the Food and Drug Administration (FDA). He has been at FDA since 1994 and during this time has served as a Clinical Team Leader in the Center for Drugs Evaluation and Research (CDER) and in the Center for Biologics Evaluation and Research (CBER). In these positions he has performed primary and secondary reviews of Investigational New Drugs and New Drug Applications (INDs and NDA/BLAs) for diagnostic and therapeutic drugs and biologics. He has also contributed to the development of regulatory policy for these products. Before joining FDA, Dr. Marzella conducted academic research in cell biology and pathology and taught at the University of Maryland School of Medicine (Department of Pathology) and at the Maryland Institute for Emergency Medical Services starting in 1980. Dr. Marzella received his clinical training at the University of Maryland (M.D.,1974; Family Medicine Residency 1977), and his graduate training at the Karolinska Institute (Ph.D.,1980 Experimental Pathology).

Dr. Louis Jacques joined CMS in 2003 and has been director of the Coverage and Analysis Group (CAG) since October 2009. The group reviews evidence and develops Medicare national coverage policy. From 2004 through 2009 he was Director of the Division of Items and Devices within CAG. Prior to his arrival at CMS, Dr. Jacques was the Associate Dean for Curriculum at Georgetown University School of Medicine, where he retains a faculty appointment. He served on a number of university committees including the Executive Faculty, Committee on Admissions and the Institutional Review Board. He previously worked in the Palliative Care program at Georgetown's Lombardi Cancer Center where he covered the gynecologic oncology service and he made home visits as a volunteer physician for a rural hospice on the Maryland Eastern Shore. Following graduation from Georgetown University in 1978, he entered the University of Maryland School of Medicine, graduating in 1982. He completed residency in 1985 and was National Health Service Corps assignee to Peoples Community Health Clinic in Waterloo Iowa for four years. From 1989 to 1995 he saw primary care patients while also holding a variety of administrative and academic positions at Henry Ford Health Systems and Wayne State University School of Medicine in Detroit. His research interests and publications focused on injury prevention, physician workforce issues, and medical education.