REGENERATIVE MEDICINE FOUNDATION

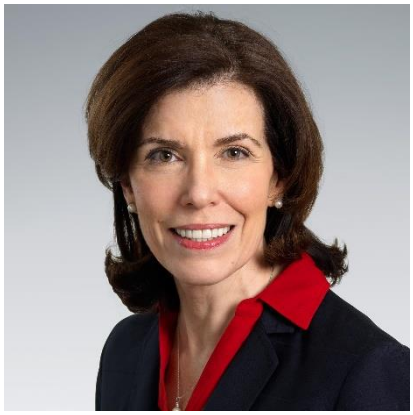
Alliance for Cell Therapy Now

CORD BLOOD ASSOCIATION

Regenerative Cell Therapies:
Making Safe and Effective Treatments Available to Patients
September 19, 2019
Our Speakers

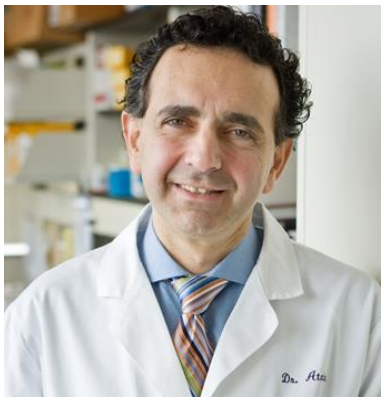
Peter Marks, MD, PhD

Peter Marks, MD, PhD serves as the Director, Center for Biologics Evaluation and Research at the Food and Drug Administration (FDA). Dr. Marks received his graduate degree in cell and molecular biology and his medical degree at New York University and completed Internal Medicine residency and Hematology/Medical Oncology training at Brigham and Women's Hospital in Boston. He has worked in academic settings teaching and caring for patients and in industry on drug development. He joined the FDA in 2012 as Deputy Center Director for CBER and became Center Director in January 2016.



Amy P. Patterson, MD

Amy P. Patterson, MD serves as the Chief Science Advisor and Director of Scientific Research Programs, Policy, and Strategic Initiatives in the Immediate Office of the Director at the National Heart, Lung, and Blood Institute within the National Institutes of Health, Dr. Patterson provides leadership and strategic coordination of trans-NHLBI efforts and manages a broad portfolio of issues germane to the conduct of clinical research, research oversight, policy development, major new scientific initiatives, and relationships with organizations within and external to the Institute. In addition, she leads the NIH efforts to implement the Regenerative Medicine Innovation Project.



Anthony Atala, M.D.

Anthony Atala, MD, is the G. Link Professor and Director of the Wake Forest Institute for Regenerative Medicine, and the W. Boyce Professor and Chair of Urology. Dr. Atala is a practicing surgeon and a researcher in the area of regenerative medicine. Dr. Atala is Editor-in-Chief of three journals, including Stem Cells Translational Medicine, and Bioprinting. Dr. Atala was elected to the Institute of Medicine of the National Academies of Sciences, to the National Academy of Inventors as a Charter Fellow, and to the American Institute for Medical and Biological Engineering. Dr. Atala is a recipient of the US Congress funded Christopher Columbus Foundation Award, bestowed on a living American who is currently working on a discovery that will significantly affect society; the World Technology Award in Health and Medicine, for achieving significant and lasting progress; the Edison Science/Medical Award for innovation; the Smithsonian Ingenuity Award; the R&D Innovator of the Year Award, and the Fast Company World Changing Ideas Award for Bioprinting Tissue and Organs. Dr. Atala's work was listed twice as Time Magazine's top 5 medical breakthroughs of the year, and once as one of 5 discoveries that will change the future of organ transplants. He was named by Scientific American as one of the world's most influential people in biotechnology, by U.S. News & World Report as one of 14 Pioneers of Medical Progress in the 21st Century, by Life Sciences Intellectual Property Review as one of the top key influencers in the life sciences intellectual property arena, and by Nature Biotechnology as one of the top 10 translational researchers in the world.

Dr. Atala has led or served several national professional and government committees, including the National Institutes of Health working group on Cells and Developmental Biology, the National Institutes of Health Bioengineering Consortium, and the National Cancer Institute's Advisory Board. He is a founding member of the Tissue Engineering Society, Regenerative Medicine Foundation, Regenerative Medicine Manufacturing Innovation Consortium, Regenerative Medicine Manufacturing Society, and Regenerative Medicine Development Organization. Over 14 applications of technologies developed in Dr. Atala's laboratory have been used clinically. He is the editor of 25 books, including Principles of Regenerative Medicine, 3D Biofabrication, Essentials of Stem Cell Biology, and Methods of Tissue Engineering. He has published more than 600 journal articles and has applied for or received over 250 national and international patents.

Joanne Kurtzberg, MD

Joanne Kurtzberg, MD serves as Director, Marcus Center for Cellular Cures (MC3); Director, Pediatric Blood and Marrow Transplant Program; Director, Carolinas Cord Blood Bank; and Co-Director, Stem Cell Laboratory at Duke University School of Medicine.

Dr. Kurtzberg is an internationally renowned expert in pediatric hematology/oncology, pediatric blood and marrow transplantation, umbilical cord blood banking and transplantation, and novel applications of cord blood in the emerging fields of cellular therapies and regenerative medicine. Dr. Kurtzberg pioneered the use of umbilical cord blood as an alternative stem cell source for unrelated hematopoietic stem cell transplantation (HSCT). Over the last two decades, Dr. Kurtzberg has established an internationally known pediatric transplant program at Duke, which treats children with cancer, blood disorders, immune deficiencies, hemoglobinopathies and inherited metabolic diseases. In 2010, Kurtzberg established the Julian Robertson Cell and Translational Therapy Program (CT2) at Duke. CT2 focuses on translational studies from bench to bedside with a focus on bringing cellular therapies in regenerative medicine to the clinic. Recent areas of investigation in CT2, which are funded by the Marcus Foundation, include the use of autologous cord blood in children with neonatal brain injury, cerebral palsy, and autism, as well as preclinical and clinical studies manufacturing microglial oligodendrocyte-like cells from cord blood to treat patients with acquired and genetic brain diseases. Studies of donor cord blood cells and donor cord tissue MSCs in adults with stroke and children with cerebral palsy and autism are also underway. In 2018, Dr. Kurtzberg established and became director of the Marcus Center for Cellular Cures (MC3) at Duke.

Dr. Kurtzberg established one of the largest unrelated donor cord blood banks, the Carolinas Cord Blood Bank, in the world at Duke in 1998. The bank has a current inventory of >40,000 units and has provided cord blood units to over 2,500 patients undergoing unrelated donor HSCT over the past 20 years. Dr. Kurtzberg's lab has developed novel assays enumerating ALDH bright cells to predict cord blood potency from segments attached to cryopreserved cord blood units, and is performing translational research testing cord blood expansion, cellular targeted therapies and tissue repair and regeneration. In 2012, under the direction of Dr. Kurtzberg, the Carolinas Cord Blood Bank received FDA approval for DuCord, a stem cell product derived from umbilical cord blood, for use in transplants between unrelated donors and recipients. Dr. Kurtzberg currently holds several INDs for investigational clinical trials. Additionally, she is the co-director of the Duke Hospital Stem Cell Transplant Laboratory.

Dr. Kurtzberg has published over 300 peer-reviewed papers, multiple chapters and scientific reviews. She is a member of the American Society of Hematology, the American Association of Blood and Marrow Transplantation, the American Society of Pediatric Hematology/Oncology, the International Society of

Cellular Therapies, the Pediatric Blood and Marrow Transplant Consortium (PBMTC), and multiple other organizations. She has served on the Board of the Foundation of Accreditation of Cellular Therapies, co-chaired the National Marrow Donor Program's Cord Blood Advisory Group and has served on the Advisory Council of Blood Stem Cell Transplantation to Health and Human Services. Dr. Kurtzberg was awarded a Lifetime Achievement Award from the PBMTC in 2012. Most recently, she established and is the first president of the Cord Blood Association.

Janet M. Marchibroda

Janet Marchibroda serves as the President of Alliance for Cell Therapy Now, a non-profit organization devoted to advancing the development, manufacturing, and delivery of both safe and effective regenerative cell therapies to patients in need. She also serves as Senior Vice President, Health Policy at the Bockorny Group and a Fellow at the Bipartisan Policy Center (BPC).

She previously served as Director of the Health Innovation Initiative and Director of the CEO Council on Health and Innovation at the Bipartisan Policy Center, a non-profit organization formed by former Senate Majority Leaders that combines the best ideas from both parties to drive the development and adoption of principled and politically viable policy. Marchibroda also served as Chief Health Care Officer for IBM, Senior Vice President for Health Policy and Technology at CNI, and Chief Operating Officer for the National Committee for Quality Assurance, a non-profit organization devoted to improving the quality of health care for Americans. Marchibroda supported the Centers for Disease Control and Prevention (CDC) in improving immunization rates through market adoption of software with immunization-related capabilities and rapidly deploying clinical, epidemiological, and data analytics teams to 38 local communities across the country to support mothers and babies impacted by the Zika crisis. She also led stakeholder engagement activities for the National Coordinator for Health Information Technology within the Department of Health and Human Services. She served as founder and CEO of the eHealth Initiative, a non-profit, multi-stakeholder member organization that was instrumental in advancing legislation that provided more than $30 billion in investments in health technology and Executive Director of Connecting for Health—an initiative supported by the Markle Foundation and Robert Wood Johnson Foundation—devoted to improving information sharing in health care. Marchibroda served as Chief Operating Officer for the National Coalition for Cancer Survivorship and co-founded and served as Chief Operating Officer of a health care-related electronic publishing, data, and consulting services company which was later acquired by Bertelsmann AG.

David Pearce, PhD

David Pearce is President of Innovation and Research for Sanford Health. He completed his undergraduate Bachelor of Science Degree with honors in biological sciences at Wolverhampton Polytechnic in 1986. He gained his PhD in 1990 at the University of Bath, UK, and did postdoctoral training at the University of Rochester, U.S., and Oxford University, UK.

Dr. Pearce heads the leading lab in Juvenile Batten disease research. He has been researching Juvenile Neuronal Ceroid Lipofuscinosis (Batten disease) since 1997. His research has led to the first clinical trial for Juvenile Batten disease. He has published over 100 research papers on Batten disease. He also oversees a national registry for rare diseases known as the Coordination of Rare Diseases at Sanford (CoRDS). He has served on numerous NIH review committees, has organized rare disease workshops for the National Institute for Neurological Disorders and Stroke (NINDS) arm of the National Institutes of Health (NIH) and is currently the vice chair of the consortium assemble for the International Rare Diseases Research Consortium (IRDiRC).

In his role as President of Innovation and Research at Sanford he is responsible for overseeing the development of research programs across Sanford's nine-state footprint, including more than 450 researchers, eight research centers and more than 300 ongoing clinical trials. With this, he is also responsible for commercialization of select research strategies, as well as integrating Sanford Research operations into Sanford Health International Clinics. Driven by Dr. Pearce's passion for developing patient-centered, impactful research programs Sanford Research is uniquely positioned to provide translational research that can bring important discoveries from bench to bedside, improving the quality of care.

Fred Sanfilippo, MD, PhD

Fred Sanfilippo MD, PhD, a well-known physician-scientist-leader, is Director of the Emory-Georgia Tech Healthcare Innovation Program, Professor of Pathology & Laboratory Medicine, Emory School of Medicine and Professor of Health Policy & Management, Rollins School of Public Health. He also serves The Marcus Foundation as Medical Director and a former Trustee.

From 2007-2010 Dr. Sanfilippo was Emory University Executive VP for Health Affairs, CEO of the Woodruff Health Sciences Center, and Board Chair of Emory HealthCare. He previously served at Ohio State University from as Senior VP for Health Sciences, CEO of the OSU Medical Center, Executive Dean for Health Sciences, Dean of the College of Medicine and Public Health and Board Chair of Managed Health Care Systems, Inc., which administered the OSU health plans.

He previously served at Ohio State University from 2000-2007 as Senior VP for Health Sciences, CEO of the OSU Medical Center, Executive Dean for Health Sciences, and Dean of the OSU College of Medicine and Public Health. At OSU he led the formation of the OSU Center for Personal Health Care, serving as its first director, and developed the Center for Integrative Health and the Department of Biomedical Informatics, which both were among the first in the country. He also was Board Chair of Managed Health Care Systems, Inc., which administered the OSU health plans and created Your Plan for Health (YP4H) a self-insured personalized health plan for all OSU faculty and staff.

From 1993 - 2000, Dr. Sanfilippo was the Baxley Professor and Director of Pathology at Johns Hopkins University, and Pathologist-in-Chief at the Johns Hopkins Hospital. He led the formation of the Johns Hopkins Medical Labs as well as the Johns Hopkins Comprehensive Transplant Center, serving as its first Director of Research. From 1979-1993 Dr. Sanfilippo was on the Duke University faculty, rising to Professor of Pathology, Surgery, and Immunology. From 1985-87 he led the creation of the national Scientific Registry of Transplant Recipients for UNOS and HRSA, which encompasses donor, recipient, and clinical follow-up data on all organs transplanted in the U.S., and is used to determine organ allocation and measure outcomes and quality of transplant programs.

Dr. Sanfilippo received BS and MS degrees in physics from Penn, his MD and PhD in immunology at Duke, and Pathology residency training at Duke. He has mentored 33 graduate students and fellows, served on 13 editorial boards, published over 250 articles, received three patents, and been awarded over $30 million in sponsored research. He has been an invited speaker at over 200 meetings, a consultant to over 80 university, government and corporate institutions, board chair of five non-profits, and president of seven academic and professional organizations including the American Society of Investigative Pathology and the American Society of Transplantation.

Bernard Siegel, JD

Bernard Siegel, J.D., is the Executive Director of the nonprofit Regenerative Medicine Foundation (RMF), with a mission of accelerating regenerative medicine to improve health and deliver cures.

Bernie founded and co-chairs the annual World Stem Cell Summit- now in its 16th year, founded and chairs the Stem Cell Action & Regenerative Medicine Awards, founded and serves as co-editor of the World Stem Cell Report (AlphaMed Press) and is founder and spokesperson for the Stem Cell Action Coalition, a 100+ member international alliance of nonprofits and research institutions supporting stem cell research.

He also serves as a member of the National Executive Leadership Council of the NSF Consortium for Advanced Manufacturing of Cell and Tissue-based Products. A consortium promoting bio-economic growth through workforce development.

In 2002, he filed the first court case relating to reproductive cloning and is widely credited for debunking the claim of the group who claimed that they cloned the first baby.

As a recognized advocacy and policy expert in the fields of stem cell research, regenerative medicine and related subjects, Bernie works with scientists, patient advocates, clinicians, industry leaders, investors and philanthropists. His efforts raise public awareness by educating lawmakers, the media and the public. His work serves as a catalyst for valuable collaborations in the field.