NATIONAL ACADEMIES *Sciences Engineering Medicine*

# *Developing a Framework to Address Legal, Ethical, Regulatory, and Policy Issues for Research Specific to Pregnant and Lactating Persons*

## *Session I* Guest Speakers

**John Beisner**
*Partner, Skadden, Arps, Slate, Meagher & Flom LLP and Affiliates*

John Beisner leads the Mass Torts, Insurance and Consumer Litigation Practice Group at the Skadden, Arps, Slate, Meagher & Flom LLP law firm. His practice focuses on the defense of class actions, mass tort controversies, and other complex civil litigation matters in both trial and appellate courts. Over the past 45 years, John has defended major corporations in more than 600 class actions. In the mass tort arena, John has handled numerous matters before the Judicial Panel on Multidistrict Litigation and has been involved in over 30 federal multidistrict litigation proceedings, typically in a lead counsel role. John is ranked in the top tier (Star Individual) in *Chambers USA: America's Leading Lawyers for Business* both in the areas of products liability and consumer class actions. In 2020, he was named a Washington, D.C. Trailblazer by *The National Law Journal*, and he has repeatedly been designated *Best Lawyers*' Washington, D.C. Mass Tort Litigation / Class Actions - Defendants Lawyer of the Year. John is a frequent writer and lecturer on class action, mass tort, and complex litigation issues, particularly as they pertain to the pharmaceutical industry.

## *Session II* Guest Speakers

**Sara E. Dyson, M.P.H., C.P.C.U.**
*Vice President of Underwriting Operations & Risk Management, Medmarc*

Sara Dyson is the Vice President of Underwriting Operations & Risk Management for the Medmarc Insurance Group, which provides products liability insurance to the life sciences industry, primarily the manufacturers and distributors of medtech and pharmaceutical products. Ms. Dyson oversees the day-to-day management of Medmarc's underwriting department, including its personnel and operations. She also manages Medmarc's risk management department, which advises life sciences companies on products liability risk management strategies and assists with related specialty areas, such as FDA compliance, post-market surveillance, product safety, and recalls. She regularly performs evaluations of life sciences products and manufacturing operations to identify products liability risks and offer solutions to control potential losses and costs. Ms. Dyson is the author of numerous articles on products liability risk management that have appeared in industry media outlets, such as *Medtech Intelligence* and *Medical Device and Diagnostic Industry* (MDDI) magazines. In 2017, Ms. Dyson joined the Editorial Advisory Board of *Medical Product Outsourcing* (MPO) magazine. Ms. Dyson earned her certification as a Chartered Property Casualty Underwriter (CPCU) in 2018. She is a member of the CPCU Society. Ms. Dyson received her law degree from the University of Wisconsin Law School and is a member of the Wisconsin and Virginia Bar Associations. She received her undergraduate degree from the University of Michigan and is currently pursuing a Master of Public Health (MPH) from the University of Missouri.

**Hillary Noll Kalay, M.P.P., J.D.**
*Principal Counsel, University of California*

Hillary Noll Kalay is Principal Counsel at the University of California's Office of General Counsel in Oakland, California, advising UC campuses and medical centers on matters relating to clinical research, data rights, privacy, and procurement. Hillary is recognized within the UC system and nationally as an expert in privacy concerns in international and domestic clinical research, and complex data collaborations. Hillary supports UC's institutional review boards, health care and research compliance, clinical research contracting, research policy, and privacy offices throughout the UC system, advising campuses and medical centers on FDA and OHRP regulations, HIPAA and GDPR, and standards for protecting rights to patient and research data. Prior to joining UC's Office of General Counsel, Hillary developed and advised on UC policies relating to clinical trials and human subject research protection. Hillary previously practiced intellectual property litigation at national law firms in San Francisco. Hillary also holds a Master of Public Policy and a CIPP/US certification.

**Elisa Hurley, Ph.D.**
*Executive Director, Public Responsibility in Medicine and Research*

Elisa A. Hurley, PhD, is the executive director of Public Responsibility in Medicine and Research (PRIM&R), leading the organization in the execution of its mission to advance the highest ethical standards in the conduct of research through educational, professional development, and public policy programs that serve the human subjects protections, animal care and use, and other research oversight communities. In addition to directing the strategic, programmatic, and operational activities of the organization, Dr. Hurley represents PRIM&R at national and international meetings, and writes, lectures, and teaches on a range of issues in research ethics. Elisa is a moral philosopher by training. Prior to arriving at PRIM&R, she was an assistant professor of philosophy at Western University in London, Ontario, Canada. Dr. Hurley received a BA in philosophy from Brown University, a PhD in philosophy from Georgetown University, and held a Greenwall Fellowship in Bioethics and Health Policy at the Johns Hopkins Berman Institute of Bioethics and Georgetown University's Kennedy Institute of Ethics. Dr. Hurley is a co-editor of the 3rd edition of *IRB Management and Function* (Jones & Bartlett, 2021). She is a member of the Consortium to Advance Effective Research Ethics Oversight (AEREO), a collaboration of leaders in human research protections aiming to evaluate and improve the effectiveness of Institutional Review Boards through empirical study, and serves on the North Star Review Board, an independent, not-for-profit learning IRB.

## *Session III* Guest Speakers

**Jason Malone, M.P.A., C.I.P.**
*Director of the Human Subjects Division, University of Washington*

Jason Malone is the Director for the Human Subjects Division at the University of Washington (UW), which manages the four Institutional Review Boards (IRBs) that review and oversee UW human subjects research. Prior to serving as Director Jason was the Assistant Director for Regulatory Affairs, administering the IRB compliance and post-approval monitoring programs. Jason spent nine years as the Clinical Compliance Officer for the UW Institute of Translational Health Sciences where he ran the compliance programs for the pediatric and adult Clinical Research Centers as well as the Data and Safety Monitoring program. Before his career at the UW, Jason spent six years at Quorum Review IRB (now Advarra) where he was responsible at various times for overseeing their nationwide site monitoring program, IRB Administration, Regulatory Compliance, and Customer Relations. Jason has a master's degree from the UW in Public Administration, and a Certificate in Global Health.

**Yvette Raphael**
*Executive Director, Advocacy for Prevention of HIV and AIDS in South Africa*

Co-founder of the new Advocacy for Prevention of HIV and AIDS (APHA) in South Africa and a leader in the country's HIV prevention movement for young women, Yvette is one of South Africa's most influential civic leaders and human rights activists. She took up the cudgels in 2000 when she was diagnosed with HIV and experienced first-hand what it means to live with the virus in a region with high levels of stigma and reduced access to health care. She has spent the past two decades on the front line, advocating for prevention education and better treatment and access to healthcare for people living with HIV (PLWHIV), specifically young women, and lesbian, gay, bisexual, trans, queer and intersex (LGBTQI) communities. A tireless campaigner, Yvette has an intimate grasp of the research and development agenda on HIV and is a member of the Global Community Advisory Group for the ECHO (Evidence for Contraceptive Options and HIV Outcomes) trial. She consults widely on policy in the workplace, assisting organizations to create better, more efficient structures to utilize the available governmental resources to end the AIDS pandemic and has lent her expertise to prevention and awareness campaigns such as Brothers for Life, Scrutinise, Four Play, Intersexions and ZAZI. In 2014, Yvette was made an AVAC Fellow in recognition of her work in the field of HIV prevention, policy and care at the Centre for Communication Impact (formerly Johns Hopkins Health and Education in South Africa). She was featured in the 2018/2019 exhibition at Smithsonian Museum entitled Out Breaks (those who survive, those left behind).

**Marcela Smid, M.D., M.A., M.S.**
*Research Participant*

Marcela Smid MD, MA, MS is a board certified Maternal Fetal Medicine and Addiction Medicine physician and Assistant Professor at the University of Utah. She is the medical director of the Substance Use & Pregnancy – Recovery, Addiction, Dependence (SUPeRAD) specialty prenatal clinic, a multi-disciplinary clinic for pregnant and postpartum individuals with substance use disorder. She has been a member of the Utah Perinatal Mortality Committee since 2016. Her research focus is on perinatal addiction, interventions for pregnant and postpartum individuals with substance use disorders, maternal mortality and maternal mental health. She is an NIH and CDC funded researcher and her studies enroll pregnant and lactating individuals into studies. Two years ago, she was also a pregnant person and enrolled in every study she met inclusion criteria including an RSV vaccine trial.

**Jillian Brown**
*Research Participant*

Jillian Brown of North Carolina has had two successful pregnancies and a previous ectopic pregnancy, and she spent over two years as a nursing and pumping mother. In 2017, in the midst of an otherwise normal pregnancy and a challenging divorce, Jillian learned that she was exposed to the cytomegalovirus (CMV) for the first time during her first trimester, putting her unborn child at risk for serious complications. As a patient in the Duke University Health System, she participated in a clinical trial throughout the remainder of her pregnancy, with continued monitoring for two years postpartum. Ultimately, the medication she received proved to be ineffective – but, fortunately, her daughter was born in excellent health and remains that way today. Jillian is now remarried with two daughters and two step-daughters, all between the ages of 5-10. A graduate of the University of Pennsylvania, she works in the Duke University Office of Information Technology, and she is passionate about protecting maternal health.

**Efthimios Parasidis, M.B.E., J.D.**
*Chief Justice Thomas J. Moyer Professorship for the Administration of Justice and Rule of Law, Ohio State University*

Efthimios Parasidis holds a joint appointment with The Ohio State University Moritz College of Law and the College of Public Health, and is a faculty affiliate with the College of Medicine's Center for Bioethics. A prolific scholar with over fifty publications, his work has appeared in top journals including the *New England Journal of Medicine*, *American Journal of Public Health*, and *American Journal of Bioethics*, among others. He is co-author of a leading graduate-level course book on the ethics and regulation of research with human subjects, and has a book on military medical ethics under contract with *Oxford University Press*. Professor Parasidis was appointed to a National Institutes of Health research ethics committee that examines complex and emerging issues in clinical data science, serves as an Ethical, Legal, and Societal Issues Team Member on DARPA's Measuring Biological Aptitude program, and served as a law and bioethics consultant to the U.S. Air Force. During the Covid-19 pandemic he served on several university, state, and local pandemic response advisory committees. In addition to his scholarly work and public service, Professor Parasidis served as an Assistant Attorney General for the State of New York, under Eliot Spitzer and Andrew Cuomo, was an associate in the Litigation group of Jones Day and a senior associate in the Intellectual Property group of Dickstein Shapiro, and is of counsel with the boutique law firm Salzano, Ettinger, Lampert & Wilson LLP.

**Renèe Gentry, J.D.**
*Principal Partner, The Law Office of Re*nèe J. Gentry

Renée J. Gentry, Esq. is one of the leading experts on vaccine injury litigation in the National Vaccine Injury Compensation Program (NVICP) with more than 20 years of practice in the NVICP. She has chaired numerous conferences on Vaccine Injury Litigation and has been a featured speaker regarding the NVICP at Judicial Conferences, Vaccine Injury Litigation Boot Camps for New Practitioners and a Court of Federal Claims Brown Bag Series on the use of experts in the NVICP. In addition to her private practice, Ms. Gentry is the Director of the Vaccine Injury Litigation Clinic at The George Washington University Law School, where she supervises student-attorneys in representing vaccine injured adults and children. Ms. Gentry has advised numerous congressional members, staff, and committees on issues relevant to the NVICP, and she has also helped to draft and introduce critical legislation to improve the NVICP. She is licensed to practice law in the District of Columbia and is admitted to the Federal Claims Court Bar where the Vaccine Court sits. She is a member of the Vaccine Injured Petitioners Bar Association, a national bar representing the interests of claimants in the NVICP, where she served as President for four years, and is currently senior counsel to the VIP Bar Board. She is also a member of the U.S. Court of Federal Claims Bar Association and previously served on its Board of Governors. She is a member of the American Association for Justice (AAJ), and its Vaccine Litigation Group.

**Michelle Mello, J.D., Ph.D.**
*Professor of Law and Health Policy, Stanford University*

Michelle Mello is Professor of Law at Stanford Law School and Professor of Health Policy in the Department of Health Policy at Stanford University School of Medicine. She conducts empirical research into issues at the intersection of law, ethics, and health policy. She is the author of more than 230 articles on medical liability, public health law, the public health response to COVID-19, pharmaceuticals and vaccines, biomedical research ethics and governance, health information privacy, and other topics. The recipient of a number of awards for her research, Dr. Mello was elected to the National Academy of Medicine at the age of 40. From 2000 to 2014, she was a professor at the Harvard School of Public Health, where she directed the School's Program in Law and Public Health. Dr. Mello teaches courses in torts, public health law, and health policy. She holds a J.D. from the Yale Law School, a Ph.D. in Health Policy and Administration from the University of North Carolina at Chapel Hill, an M.Phil. from Oxford University, where she was a Marshall Scholar, and a B.A. from Stanford University.

**Metin Gülmezoğlu, *M.D.***
*Executive Director, Concept Foundation*

Metin Gülmezoğlu is an obstetrician gynaecologist who worked in Turkey, South Africa, United Kingdom and Switzerland. He is currently the Executive Director of Concept Foundation, a nonprofit nongovernmental organization working on improving access to quality-assured sexual and reproductive health medicines and technologies in low- and middle-income countries worldwide based in Geneva, Switzerland and Bangkok, Thailand. Prior to joining Concept Foundation, Metin was working at HRP (the UNDP/ UNFPA/ UNICEF/ WHO/ World Bank Special Programme of Research, Development and Research Training in Human Reproduction), World Health Organization, as the Coordinator for Maternal and Perinatal Health and Abortion. Metin published more than 300 articles and book chapters and gave numerous presentations in global, regional and national conferences and meetings. Metin is an honorary fellow of the Royal College of Obstetricians and Gynaecologists in the UK, honorary member of The Society for Maternal Fetal Medicine in the U.S.A. and holds an honorary professorship at the Institute of Metabolism and Systems Research, University of Birmingham, U.K.

**Niranjan Bhat, M.D., M.H.S.**
*Senior Medical Officer, PATH*

Niranjan Bhat, MD, MHS, is a senior medical officer and Team Lead for Vaccine Impact Research within the Center for Vaccine Innovation and Access at PATH. Dr. Bhat's research focuses on post-licensure evaluations of vaccines in low- and middle-income countries, including assessments of vaccine impact, effectiveness and safety to support improved access in underserved populations. His current and recent research includes clinical trials and observational studies of vaccines against rotavirus, HPV, meningococcus, and COVID. In the field of maternal immunization, Dr. Bhat has overseen trials in Thailand to evaluate an acellular pertussis vaccine for use in pregnant women, and has worked with the WHO on maternal influenza immunization and overall maternal immunization safety in low-resource settings. Dr. Bhat received his A.B. from Harvard College, M.D. from Vanderbilt University, did his pediatrics residency at the University of Washington, and completed a M.H.S. and fellowship in pediatric infectious diseases at Johns Hopkins University. In addition, he received training as a medical epidemiologist at CDC and served as a clinical reviewer in the Office of Vaccines, FDA.

**Lorien Urban, Ph.D.**
*Senior Medical Director Clinical Development, Ferring Pharmaceuticals*

Lorien Urban has spent over 20 years conducting clinical research primarily within the pharmaceutical and medical device industries. She holds a PhD in Biochemical and Molecular Nutrition from Tufts University where she conducted research on preventing excess weight gain during pregnancy. She is currently a Senior Medical Director within Clinical Development at Ferring Pharmaceuticals and led a program to develop a treatment for mothers experiencing low milk supply. A leader in reproductive medicine and maternal health, Ferring has been developing treatments for mothers and babies for over 50 years.