# NIH Workshop on Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer

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Participant Biographies

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## Reid Adler, JD

Chief Corporate Development Officer and General Counsel, Vistagen

*Panelist: How NIH Negotiates License Terms*

Reid Adler, J.D. joined Vistagen as General Counsel in May 2022. During his extensive career in the biopharma sector, Mr. Adler was a senior partner at two international law firms, Morrison & Foerster and Morgan Lewis, and the general counsel to the pioneering J. Craig Venter Institute for genomics research. While in private practice before joining Vistagen, he consulted with several major biopharmaceutical companies on product exclusivity and for the Coalition for Epidemic Preparedness Innovations (CEPI) on legal and business aspects of vaccine development. Earlier, he was the founding director of the NIH Office of Technology Transfer, which facilitated the translation of tax-payer-funded research results into healthcare products.

Mr. Adler received a Bachelor of Science degree from the University of Maryland, College Park, and a Juris Doctor degree from the George Washington University. He has testified before the U.S. Congress, published widely, and taught graduate courses about innovation management, strategic planning, and biotechnology law and policy. At NIH, he played a key role in expanding relationships with industry, developing technology-related policies and model contractual agreements, and contributing to the research integrity guidelines and the Uniform Biological Material Transfer Agreement, currently used by hundreds of organizations worldwide.

## Sue Ano, PhD

Director, Technology Transfer Office, National Institute of Neurological Disorders and Stroke

*Presenter: How NIH Identifies and Evaluates Licensees*

Sue has been an active member of the NIH technology transfer community since 2002, where she has facilitated the advancement of scientific endeavors through collaborations, patenting, licensing, and other means. She is proud to lead a team of professionals dedicated to the advancement of science using tech transfer mechanisms, focusing on best-fit solutions to achieve positive outcomes. Prior to her current position, Sue was a technology licensing specialist and branch chief, giving her an extensive range of tech transfer experiences from multiple vantage points within the NIH infrastructure and resulting in several NIH awards for her achievements. With a Ph.D. from the Department of Chemistry at Emory University and B.S. in chemistry from the University of Delaware, Sue has a firm foundation established on which to broaden her scientific knowledge to include neurological disorders and infectious diseases in addition to a sound framework for application of other relevant aspects, including legal, business, and policy. Sue is passionate about facilitating partnerships and other activities to ensure that NINDS and NIH can accomplish our mission to apply scientific knowledge to enhance health and reduce illness and disability.

## Margo Bagley, JD

Vice Dean and Asa Griggs Candler Professor of Law, Emory University School of Law

*Panelist: How NIH Chooses What to Patent and License*

Margo A. Bagley is Asa Griggs Candler Professor of Law at Emory University School of Law. She rejoined the Emory faculty in 2016 after a decade at the University of Virginia School of Law, where she was most recently the Hardy Cross Dillard Professor of Law. In fall 2022, she was the Hieken Visiting Professor in Patent Law at Harvard Law School.

Bagley is a well-known and widely cited scholar on a variety of international intellectual property topics and is one of the foremost experts on international patent law issues. At Emory, her courses include Domestic and International Patent Law, Trademark Law, and International Intellectual Property. She also co-developed the award-winning TI:GER® program (Technological Innovation Generating Economic Results), an innovative educational venture which brings together graduate students in law, business, science, and engineering to work on start-up projects and learn the process of transforming promising research into economically viable projects.

Bagley received her JD in 1996 from Emory, where she was a Robert W. Woodruff Fellow, an editor of the *Emory Law Journal*, and elected to Order of the Coif. She is a member of the Georgia bar and is licensed to practice before the US Patent and Trademark Office. Bagley worked as an associate with Smith, Gambrell & Russell, LLP and Finnegan, Henderson, Farabow, Garrett & Dunner, LLP before becoming an assistant professor of law at Emory University in 1999 and associate professor in 2002. She was a visiting professor of law at Washington & Lee University School of Law in fall 2001 and at the University of Virginia School of Law in fall 2005, after which she joined the University of Virginia faculty in 2006. She is a faculty lecturer with the Munich Intellectual Property Law Center at the Max Planck Institute in Germany, and also has taught International Patent Law and related courses in China, Cuba, Israel, and Singapore.

Bagley recently served on the National Academies Committee on Advancing Commercialization from the Federal Laboratories, and previously served on the National Academies Committee on University Management of Intellectual Property: Lessons from a Generation of Experience, Research, and Dialogue. She is also an expert technical advisor to the African Union Commission in several World Intellectual Property Organization (WIPO) matters, is the Friend of the Chair in the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, and is a collaborator with the Harvard University Global Access in Action Program.

Bagley has served as a consultant to the UN Convention on Biological Diversity (CBD), the UN Food and Agriculture Organization Secretariat for the International Treaty on Plant Genetic Resources for Food and Agriculture, and as a US Department of Commerce Commercial Law Development Program advisor. In addition, she served as a member of the Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources for the CBD and Nagoya Protocol and has been an expert witness in several patent law disputes. Her scholarship focuses on comparative issues relating to patents and biotechnology, pharmaceuticals and access to medicines, traditional knowledge protection for indigenous peoples and local communities, technology transfer, and IP and social justice. In 2018,

Professor Bagley was awarded and managed a $50,000 Emory Global Health Institute grant for a drug quality assurance program in Mozambique/Malawi, which involved a successful collaboration with the Harvard Global Access in Action (GAiA) program and the Emory-Rollins School of Public Health.

Bagley has published numerous articles and book chapters, as well as two books with co-authors: Bagley, Okediji and Erstling, *International Patent Law & Policy* (West Publishing 2013) and *Patent Law in Global Perspective* (Okediji and Bagley eds., Oxford University Press 2014). A new book on International Patent Law is forthcoming with Professor Rochelle Dreyfuss (2023). A chemical engineer with a B.S.Ch.E. degree from the University of Wisconsin-Madison, Bagley worked in industry (with the Procter & Gamble Company and the Coca Cola Company) for several years before attending law school and is a co-inventor on two patents, one for reduced fat peanut butter and the other for improved bedding technology. Bagley also completed research internships at Oak Ridge National Laboratory, Lawrence Livermore National Laboratory, AT& T Bell Laboratories, and the NASA Marshall Space Flight Center.

## Krishna Balakrishnan, PhD

Director, Office of Strategic Alliances, National Center for Advancing Translational Sciences
*Panelist: How NIH Negotiates License Terms*

Krishna (Balki) Balakrishnan is the director of NCATS' Office of Strategic Alliances (OSA), where he oversees the Center's partnership, strategic alliance and technology transfer functions and leads a team of licensing and patenting specialists who collectively work with the Center's scientific staff to facilitate their collaborative efforts. Balakrishnan and his team assist in all aspects of developing these strategic alliances, including helping define the contours of the collaboration, delineating roles and responsibilities for the various parties and troubleshooting any challenges that may occur during the collaborations. His team is responsible for protecting NCATS' intellectual property and for helping commercialize the Center's discoveries through licensing and partnerships. Balakrishnan also is the program director for the NCATS Small Business Innovation Research (SBIR) and Small Business Technology Transfer Research (STTR) grant and contract programs. In this role, he works closely with interested small businesses by providing advice and educational resources about the program. The OSA is unique in managing both the SBIR and STTR programs within one team and deriving valuable synergies by doing so.

Before joining NCATS in 2011, Balakrishnan served as executive director at the Foundation for Advanced Education in the Sciences, a nonprofit foundation affiliated with NIH, where he greatly expanded the academic offerings by establishing certificate programs in technology transfer and public health. His earlier positions at NIH include marketing group leader in the NIH Office of Technology Transfer and senior technology development manager at the National Heart, Lung, and Blood Institute. Prior to his tenure at NIH, Balakrishnan was vice president of technology and business development and vice president of research and development at a division of Covance, formerly Berkeley Antibody Company.

Balakrishnan earned his doctorate in biophysical chemistry from Stanford University and his master's in business administration from the University of California, Berkeley. He is the co-inventor on two U.S. patents (including US 6,750,328B1) and has published and presented extensively on scientific subjects and technology transfer matters.

## Julia Barnes-Weise, JD

Executive Director, Global Healthcare Innovation Alliance Accelerator; Senior Consultant, Coalition for Epidemic Preparedness Innovations

*Panelist: How NIH Negotiates License Terms*

Julia Barnes-Weise is the founder and Executive Director of the Global Healthcare Innovation Alliances Accelerator (GHIAA), a non-profit organization that develops and promotes the use of tools and best practices for global health alliance formation. In this capacity she has also been a senior consultant to CEPI for almost six years.

She is a lawyer, global health policy consultant, entrepreneur and Certified Licensing Professional. Formerly, Barnes-Weise had a faculty appointment in the Duke Sanford School of Public Policy and was previously a Director of Business Development at Glaxo Wellcome (now GSK). She has decades of experience negotiating IP licenses & alliance agreements and advising companies and institutions on partnering strategies.

Her educational background includes a Juris Doctor degree from the University of North Carolina, a year at the Notre Dame London Law Centre studying international trade law, a BA from Ohio Wesleyan University, and an executive program at Duke University's Fuqua Business School in International Marketing Leadership.

She is a board member of the Licensing Executives Society and a former board member of the Medical University of South Carolina Foundation for Research and Development. She also serves on several task forces and has published articles on topics related to global public health security.

## Penny Burgoon, PhD

Director of Policy, Communications and Education, National Center for Advancing Translational Sciences
*Moderator: How NIH Identifies and Evaluates Licensees*

Penny Burgoon, Ph.D., is the director of the Office of Policy, Communications and Education (OPCE), where she has focused the Office's efforts on strategic policy and communications, with an emphasis on educating others about and disseminating information on the value of effective translational science to benefit research. She joined NCATS in July 2014 as the chief of the Science Policy Branch, served as the acting director of OPCE in 2016, and was appointed permanent OPCE director in 2018.

Prior to her tenure at NCATS, she was the director of the Salivary Biology and Immunology Program for the National Institute of Dental and Craniofacial Research, where she managed a portfolio of research in salivary biology, salivary gland disorders and diseases. Burgoon joined NIH in 2004 as an American Association for the Advancement of Science AAAS Science Policy Fellow, providing program support for the first NIH-wide projects supported through the NIH Roadmap for Medical Research, now known as the NIH Common Fund. She then served as the senior assistant to the NIH principal deputy director from 2006 to 2010, coordinating activities across several NIH leadership committees, including the NIH Steering Committee, the NIH Advisory Committee to the Director, and Institute and Center Directors' meetings. Throughout her NIH career, she has been a member of numerous committees, serving all of NIH or its individual Institutes and Centers.

Burgoon received her bachelor's degree from Oberlin College, her master's degree from California State University, Northridge, and her doctorate in physiology from The Ohio State University.

## Andrew Burke, PhD

Senior Technology Transfer Manager, Technology Transfer Center, National Cancer Institute

*Presenter: How NIH Identifies and Evaluates Licensees*

Dr. Andrew Burke is a Senior Technology Transfer Manager for the National Cancer Institute's (NCI) Technology Transfer Center. He joined the office in July 2013. In his current position, he manages a portfolio of intellectual property and related licenses covering the research of Dr. Steven A. Rosenberg, Chief of Surgery, and the investigators and staff of NCI Surgery Branch. His efforts in this regard have resulted in regional and national awards, including a 2020 and 2018 national citation for "Excellence in Technology Transfer" from the Federal Laboratory Consortium and the 2016 technology transfer "rookie of the year" award for the mid-Atlantic region. Prior to joining NIH technology transfer operations, Andrew was a Cancer Genetics and Signaling Fellow at NCI-Frederick in the lab of Dr. Brad St. Croix. Andrew received his Ph.D. in Cancer Biology from Wake Forest University School of Medicine under the direction of Drs. Frank and Suzy Torti with a dissertation describing the use of multiwalled carbon nanotubes for the photothermal treatment of cancer. He received a B.A. degree in Biology from Pepperdine University.

## Almesha Campbell, PhD

Assistant Vice President for Research and Economic Development, Jackson State University; Chair, Board of Directors, AUTM

*Panelist: How NIH Chooses What to Patent and License*

Almesha L. Campbell, Ph.D. is the Assistant Vice President for Research and Economic Development at Jackson State University (JSU). In this capacity, she supports the Vice President with overall responsibility for the Division of Research and Economic Development. For over 10 years, she served as the Director for Technology Transfer and Commercialization at JSU and continues to manage the intellectual property process from triage of invention disclosures to commercialization.

Almesha designs and manages a number of national and local programs around innovation and entrepreneurship in an effort to broaden the participation of underrepresented minorities in these areas. She is the Principal Investigator (PI) for the NSF-supported JSU I-Corps Site, which is designed to train teams of faculty and students to take their ideas from the lab to the market. She is also PI of two NSF EAGER grants: One is designed to help change the perception of underrepresented minorities in innovation and entrepreneurship, and the other is focused on creating a pathway to commercialization at HBCUs. Almesha serves as the executive director of the NIGMS-funded Engaging Researchers and Innovators in Commercialization at HBCUs (EnRICH) pre-accelerator program. She co-led the development of the newly established Center for Innovation and Entrepreneurship at JSU, which houses XR Academy, makerspace, eSports Lab, learning collaboratory, production room, and more. She created the JSU Innovation Fellows Program and spearheads a newly designed initiative to transform the STEM curriculum using virtual reality.

She was elected chair of the AUTM Board of Directors – the first black person and the first from an HBCU to sit on the Board. In addition to AUTM, Almesha holds membership in professional organizations such as the Licensing Executives Society, Society of Research Administrators (SRA) International, and the American Society of Public Administration and is an honorary member of the National Academy of Inventors. She has a bachelor's degree from the University of Central Florida, a master's degree in mass communications, and a doctoral degree in public policy and administration from Jackson State University.

## Rena Conti, PhD

Associate Professor, Department Of Markets, Public Policy, And Law, Questrom School Of Business, Boston University

*Panelist: How NIH Identifies and Evaluates Licensees*

Rena Conti is a Technology & Policy Research Initiative (TPRI) Faculty Director and is an Associate Professor at the Boston University Questrom School of Business. From July 2018 through December 2021, Professor Conti served as Associate Research Director of Biopharma & Public Policy for Boston University Institute for Health System Innovation & Policy. Prior to BU, from 2006 through June 2018, Professor Conti was an Associate Professor of Health Economics and Policy at the University of Chicago Medical School and the Harris School of Public Policy. Dr. Conti is a health economist. Her research focuses on the organization, financing and regulation of medical care. She has written extensively on the pricing, demand and supply of prescription drugs.

## Maryann Feldman, PhD

Watts Endowed Professor of Public Affairs, Arizona State University School of Public Affairs

*Panelist: Perspectives from the Public and Private Sector*

Maryann serves as the Watts Endowed Professor of Public Affairs at Arizona State University School of Public Affairs.

From 2008 to 2022 she taught as the S.K. Heninger Distinguished Professor of Public Policy at UNC-Chapel Hill's Department of Public Policy and from 2017 to 2022 was an adjunct professor of finance at UNC Kenan-Flagler Business School. In addition, Maryann served as the faculty director of CREATE. Her research and teaching focus on the geography of innovation, the commercialization of academic research and the factors that promote technological change and economic growth.

Among her honors, Maryann was awarded the 2013 Global Award for Entrepreneurship Research. She is the editor of Research Policy, and has written for numerous journals, including the American Economic Review and The Brookings Papers on Economic Policy.

Maryann earned a doctorate in economics and management and a master's degree in public policy analysis from Carnegie Mellon University. She also holds a bachelor's degree from Ohio State University.

## Gillian Fenton, JD

Special Counsel for Innovation and Government Collaborations, GSK

*Panelist: How NIH Identifies and Evaluates Licensees*

Gillian M. Fenton, Esq., CLP has been a member of the Licensing Executives Society (LES, USA & Canada) since 1992, and served as the society President in 2020-2021. Gillian's contributions to LES and to the field of licensing were recognized with the society's Frank Barnes Award in October, 2022. She is presently a member of the LES Public Policy Committee and is a volunteer instructor in LES educational courses.

Gillian is presently Special Counsel for Innovation and Government Collaborations at GSK. Her practice includes a wide variety of business development transactions, R&D collaborations and nondilutive funding agreements with U.S. Government entities (NIH/NIAID, BARDA, CARB-X, and DARPA), all in support of GSK's vaccines pipeline and platform technologies. Prior to joining GSK, Gillian was VP, Associate General Counsel & Chief Intellectual Property Counsel at Emergent BioSolutions Inc., where she founded the IP department and supported all IP aspects of the company's IPO and subsequent 9 years of growth through M&A in the vaccines, biodefense, and global health fields. Gillian also spent over ten years in private practice at law firms in Boston, MA and Washington, DC.

Education: J.D. *cum laude*, Suffolk University Law School; B.Sc. Biochemistry, Trinity College.
Admissions: MA, MD, DC. Registered U.S. Patent Attorney.

## Maria Freire, PhD

Principal, The Freire Group

*Keynote Speaker*

Dr. Maria Freire is Founder and Principal of The Freire Group, a consulting firm focusing on strategic alliances in the life sciences. Until September 2021, Dr. Freire was President and Executive Director, and a member of the board of directors, of the Foundation for the National Institutes of Health, a Congressionally authorized independent organization that draws together the world's foremost researchers and resources in support of the mission of the National Institutes of Health (NIH). From 2008 to 2012, Dr. Freire was the President of the Albert and Mary Lasker Foundation, which bestows the Lasker Awards in basic and clinical science and advocates for medical research. From 2001 to 2008, Dr. Freire served as President and Chief Executive Officer of the Global Alliance for TB Drug Development (TB Alliance), a public-private partnership that develops better, faster-acting and affordable drugs to fight tuberculosis. An expert in technology commercialization, she directed the Office of Technology Transfer at the NIH from 1995 to 2001.

Dr. Freire served on, and chaired, the Science Board of the Food and Drug Administration and was a member of the World Health Organization Commission on Intellectual Property Rights, Innovation and Public Health. She was appointed to the United Nations Secretary General's High-Level Panel on Access to Medicines, and served as a member of the Institute of Medicine Commission on a Global Health Risk Framework for the Future. Her awards include the Department of Health and Human Services Secretary's Award for Distinguished Service, the Arthur S. Flemming Award, the Bayh-Dole Award, the 2017 Washington Business Journal's *Women Who Mean Business* Award, the 2017 Gold Stevie Award for *Woman of the Year*, the NonProfit PRO's 2019 *Executive of the Year* Award and was selected as one of the 2023 *Great Immigrants Great Americans* by the Carnegie Corporation of New York.

She is currently a member of the Board of Directors at Alexandria Real Estate Equities, Exelixis, Biogen, Koneksa Health, the Keystone Symposia and Chair of the Business Advisory Board of the Institute for Research in Biomedicine in Barcelona, Spain (IRB Barcelona). Dr. Freire obtained her Bachelor of Science degree from the Universidad Peruana Cayetano Heredia in Lima, Peru, and her Ph.D. in Biophysics from the University of Virginia. She is a member of the U.S. National Academy of Medicine and the Council on Foreign Relations.

## Lyric Jorgenson, PhD

Acting Associate Director for Science Policy, NIH

Lyric Jorgenson is the Acting Associate Director for Science Policy and the Acting Director of the Office of Science Policy at the NIH. In this position, she provides senior leadership in the development and oversight of cross-cutting biomedical research policies and programs considered to be of high-priority to NIH and the United States Government.

Prior to this role, she served in numerous roles across the agency, including Deputy Director of the Office of Science Policy, and has led the development of numerous high impact science and policy initiatives such as the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative and the National Center for Advancing Translational Sciences (NCATS). Dr. Jorgenson also served as the Deputy Executive Director of the White House Cancer Moonshot Task Force in the Office of the Vice President in the Obama administration, where she directed and coordinated cancer-related activities across the Federal government and worked to leverage investments across sectors to dramatically accelerate progress in cancer prevention.

Lyric received a doctorate degree from the Graduate Program for Neuroscience at the University of Minnesota-Twin Cities where she conducted research in neurodevelopment with a focus on learning and memory systems. She earned a Bachelor's degree in Psychology from Denison University.

## Maria Kefalas, PhD

Founder, The Calliope Joy Foundation; Professor, Department of Sociology and Criminal Justice, Saint Joseph's University

*Panelist: Perspectives from the Public and Private Sector*

Maria Kefalas studied economics at Wellesley College and earned her M.A. and Ph.D. in sociology from the University of Chicago. She worked at the Brookings Institution, held a post-doctoral fellowship at the University of Pennsylvania, and taught at Barnard College (Columbia University) before joining the faculty of Saint Joseph's University in Philadelphia. Kefalas is the author of numerous books and articles, and has received grants from the William T. Grant Foundation, the MacArthur Foundation, and the Department of Justice.

Her life took an unexpected turn in 2012 when her husband, father, and father-in-law were all diagnosed with cancer. That same year, on the fifth of July, she learned her youngest child, Calliope "Cal", suffered from a fatal degenerative neurological disease called metachromatic leukodystrophy (or MLD). Leukodystrophies are in the same family as Tay-Sachs and Canavan diseases. Cal would lose the ability to walk, talk, and feed herself within months. Cal was not expected to survive beyond the age of six. Kefalas gained fifty pounds and struggled with depression and grief.

Then, a year after her daughter's diagnosis, Cal's nine-year-old brother PJ suggested that the family start selling cupcakes "to raise money and to help kids like Cal." This idea for a bake sale would change everything. She started blogging under the name "The Recovering Supermom" and published essays in *Slate*, *STAT*, *The Mighty*, and *The Huffington Post*. With her husband, Pat Carr, Kefalas is the co-founder of the Calliope Joy Foundation and Cure MLD.

Over the next several years, the family would sell 50,000 cupcakes. That money would help establish the nation's first Leukodystrophy Center of Excellence at the world-renowned Children's Hospital of Philadelphia. She has become a nationally recognized parent advocate for gene therapy who has spoken at the NIH, NORD, and the FDA.

Tragically, Kefalas's husband, Rutgers University sociologist Pat Carr died from multiple myeloma on April 16, 2020. Cal would beat the odds for over a decade. Cal succumbed to the disease at the age of 12 on March 24th, 2022. She was surrounded by her family, nurses, and doctors at her home. She left this world while her brother PJ held her in his arms.

The story of Cal and the cupcakes has been featured on CBS Sunday Morning with Jane Pauley and the Chan Zuckerberg Initiative. Kefalas's work was funded by the Philadelphia Eagles, and she received the 2018 Rare Impact Award by National Organization of Rare Disorders (NORD).

Her latest book *Harnessing Grief: One Mother's Quest for Meaning and Miracles* was published by Beacon Press.

Maria and her family continue to sell cupcakes and they have raised over a million dollars to help children impacted by leukodystrophies. Libmeldy, a gene therapy to treat Cal's disease, was approved in

the EU and UK in 2021. That same year, the state of New York began screening newborns for MLD. And Maria is working tirelessly to ensure that MLD will become one of the five percent of rare diseases with an FDA approved treatment in the near future.

Maria has embraced a healthy lifestyle with the help of her family and she only sells cupcakes these days, but rarely eats them anymore herself.

She lives outside of Philadelphia with her children Camille and PJ and a rescued dog named Brody. Camille recently graduated from the College of Wooster with a degree in sociology and religion and has been inspired to work in the health care field because of Cal. PJ is a transfer student at Rutgers University studying biochemistry, he hopes to use his degree in science to join the fight against genetic diseases like leukodystrophy. Maria is a professor at Saint Joseph's University.

## Tara Kirby, PhD

Director, Office of Technology Transfer, NIH

*Presenter: How NIH Negotiates License Terms*

Tara Kirby has been the Director of the Office of Technology Transfer (OTT) since 2020. Previously, she supervised the CDC Team at the NIAID Technology Transfer and Intellectual Property Office from 2015 to 2020. Dr. Kirby also worked at OTT from 2006 to 2015, starting as a postdoctoral fellow and ultimately assuming the role of CDC unit chief. Her research experience includes postdoctoral research at the National Institute of Diabetes and Digestive and Kidney Diseases investigating *Y. pestis* membrane protein structure, as well as pre-doctoral and postdoctoral research at the University of Minnesota focused on structure/function relationships of cardiac membrane proteins. Dr. Kirby received a B.S. degree in Chemistry from the California Institute of Technology and a Ph.D. degree in Biochemistry, Molecular Biology, and Biophysics from the University of Minnesota.

## James Love

Director, Knowledge Ecology International

*Panelist: How NIH Negotiates License Terms*

James Love is Director of Knowledge Ecology International. His training is in economics and finance, and work focuses on the production, management and access to knowledge resources, as well as aspects of competition policy. The current focus is on the financing of research and development, intellectual property rights, prices for and access to new drugs, vaccines and other medical technologies, as well as related topics for other knowledge goods, including data, software, other information protected by copyright or related rights, and proposals to expand the production of knowledge as a public good. James Love holds a Masters of Public Administration from Harvard University's Kennedy School of Government and a Masters in Public Affairs from Princeton's Woodrow Wilson School of Public and International Affairs.

He advises UN agencies, national governments, international and regional intergovernmental organizations and public health NGOs, and is the author of a number of articles and monographs on innovation and intellectual property rights.

## Peter Maybarduk, JD

Access to Medicines Director, Public Citizen

*Panelist: How NIH Chooses What to Patent and License*

Peter Maybarduk directs Public Citizen's access to medicines group, which helps partners worldwide make medicine available and affordable for all. Maybarduk is an intellectual property expert and is available to speak about drug pricing, innovation policy, pandemic readiness and global health. Since 2010 the access group's work has helped shape major medicine pricing legislation and executive action in the United States and abroad, reduce the price of key medicines, conserve health budgets, change the course of international trade negotiations, facilitate technology licensing, empower public agencies, discipline prescription drug corporations, and support a more robust and equitable global response to Covid-19.

Maybarduk has provided technical and strategic assistance to government agencies and health organizations in dozens of countries. He facilitates U.S. and global civil society alliances on access to medicines. Maybarduk's commentary frequently appears in papers of record, including *The New York Times* and *The Washington Post*. He sits on the governance board of the Medicines Patent Pool, a United Nations-backed organization that negotiates licenses among drugmakers to expand global availability of affordable generics. Maybarduk studied technology law at the University of California at Berkeley and anthropology at The College of William and Mary in Virginia. He is an affiliate fellow with the Information Society Program at Yale Law School. Maybarduk founded International Professional Partnerships for Sierra Leone, a non-profit dedicated to supporting public sector development in one of the world's least developed countries.

## Matt McMahon, PhD

Director, NIH Small Business Education & Entrepreneurial Development Office

*Moderator: How NIH Negotiates License Terms*

Matt McMahon leads the Small Business Education & Entrepreneurial Development (SEED) Office in helping to transform cutting-edge technologies into products that improve health and save lives. He previously served as the first director of the National Heart, Lung, and Blood Institute's Office of Translational Alliances and Coordination, and he created and led the National Eye Institute's Office of Translational Research. His previous experience also includes service as the principal scientist for the bionic eye company Second Sight Medical Products and as a staff member on both the United States Senate and House of Representatives committees responsible for science, technology, and innovation policy.

## Justin Mendoza, MPH

Executive Director, North America, Universities Allied for Essential Medicine

*Panelist: Perspectives from the Public and Private Sector*

Before joining UAEM North America as Executive Director, Justin led Partners In Health United States' efforts on domestic policy and advocacy strategy, where he worked on legislative policy changes in the American Rescue Plan Act and advocated for a rational COVID-19 response. Previously, Justin worked on health care priorities with Families USA and Public Citizen in Washington D.C., focused on lowering drug prices, taking on pharmaceutical patent overreach, expanding health care coverage, and lowering underlying health care costs. Justin holds an MPH in Health Policy from Yale University and a B.S. in biomedical sciences and neuroscience from Central Michigan University.

## Matthew Miessau

Senior Associate, Epidarex Capital

*Panelist: How NIH Identifies and Evaluates Licensees*

Matthew Miessau is a Senior Associate with Epidarex Capital, a Bethesda, Maryland based venture capital firm that finds, invests in, and builds early-stage breakthrough life sciences companies in emerging hubs. Matthew is actively involved in deal sourcing, including expanding Epidarex Capital's reach and relationships with key universities in the US. He is focused on conducting due diligence on prospective investments on both sides of the Atlantic, assisting in portfolio management, and supporting the firm's fundraising efforts. Matthew serves as a Director for Clyde Biosciences and is a Board Observer for AdoRx Therapeutics and Epidarex Exeed. In addition, Matthew is also currently an instructor at the NIH Foundation for Advanced Education in the Sciences (FAES) and serves on multiple university commercialization advisory and review boards. Matthew holds an M.S. in Biotechnology and a B.S. in Biochemistry from Georgetown University.

## Anji Miller, MSc, PhD

LifeArc and Skills Lead for Innovation Hubs for Gene Therapy, Senior Business Manager, LifeArc

*Panelist: Perspectives from the Public and Private Sector*

Anji is a TT professional with more than 19 years' experience of working with early-stage translational research. Anji has extensive experience of IP and contract management, licensing, business development of healthcare technologies and development of knowledge transfer policies. Her current role at LifeArc involves working with academic and charitable establishments to identify, cultivate, fund and commercialise early-stage healthcare technologies, focusing on rare diseases and the advanced therapies.

A proponent for professional advancement in STEM careers, Anji is active in many initiatives missioned to address the current UK skills gap and training shortage. These include leadership of the LifeArc-AUTM TT Training Fellowship and LifeArc TTO Fellowship programmes, designed to train and assist scientists to become TT professionals; directing LifeArc's translational placement and training programmes, and working with external partners to improve STEM learning and development in education. As the Skills Lead for recently launched Innovation Hubs for Gene Therapy, Anji works with the Innovation Hubs to address the identified skills needs in the advanced therapy sector.

An advocate of equality, diversity and Inclusion, Anji cofounded Global Equality, Diversity and Equality in Technology Transfer (GEDITT), an initiative missioned to raise awareness and promote EDI in the TT sector.

Anji holds an M.Sc. in Human Molecular Genetics and Ph.D. in Cancer Genetics from Imperial College, and M.Sc. and Certificate in IP Law from QMUL. She is a certified project manager, Registered Technology Transfer Professional and Certified Licensing Professional.

Anji is a board member of AUTM, The Alliance of Technology Transfer Practitioners (ATTP), ASTP, Certified Licensing Professional (CLP) and a member of the BioIndustry Association (BIA) Cell & Gene Therapy Advisory Committee, and the AUTM Equity, Diversity & Inclusivity Committee.

## Lisa Larrimore Ouellette, JD, PhD

Deane F. Johnson Professor of Law, Stanford Law School; Senior Fellow, Stanford Institute for Economic Policy Research

*Panelist: How NIH Chooses What to Patent and License*

Lisa Larrimore Ouellette is the Deane F. Johnson Professor of Law at Stanford Law School, as well as a Senior Fellow at the Stanford Institute for Economic Policy Research. Her scholarship addresses empirical and theoretical problems in intellectual property and innovation law. She takes advantage of her training in physics to explore policy issues such as how scientists use the technical information in patents, how scientific expertise might improve patent examination, the patenting of publicly funded research under the Bayh–Dole Act, and the integration of IP with other levers of innovation policy. She has applied these ideas to biomedical innovation challenges including the opioid epidemic, the COVID-19 pandemic, and pharmaceutical prices. She has also written about multiple legal issues in trademark law, about the evidentiary value of online surveys, and about the potential for different standards of review to create what she terms "deference mistakes" in numerous areas of law.

Professor Ouellette is also an acclaimed teacher and nationally recognized intellectual property law expert. She has coauthored a free patent law casebook, *Patent Law: Cases, Problems, and Materials*. She has written over 350 posts for her blog, *Written Description*, and her commentary has appeared in publications including the *New York Times*, *Wall Street Journal*, *TIME Magazine*, and *Slate*. She has been selected to design and lead pedagogy training for other Stanford Law faculty. In 2018, she received the law school's John Bingham Hurlbut Award for Excellence in Teaching.

Prior to her appointment at Stanford Law School in 2014, Professor Ouellette was a Postdoctoral Fellow at the Information Society Project at Yale Law School. She also clerked for Judge Timothy B. Dyk of the U.S. Court of Appeals for the Federal Circuit and Judge John M. Walker, Jr. of the U.S. Court of Appeals for the Second Circuit. She holds a J.D. from Yale Law School, where she was an Articles Editor of the *Yale Law Journal* and a Coker Fellow in Contract Law. She earned a Ph.D. in physics from Cornell University as well as a B.A. in physics from Swarthmore College, and she has conducted scientific research at the Max Planck Institute, CERN, and NIST.

## Amy Petrik, PhD

Senior Technology Transfer and Patent Specialist, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases

*Presenter: How NIH Chooses What to Patent and License*

Amy Petrik works as a senior technology transfer and patent specialist at NIAID's Technology Transfer and Intellectual Property Office. Amy earned a bachelor's of science degree in chemistry at the University of Pittsburgh. She earned her doctoral degree in physical chemistry studying the photodynamics of conjugated polymers at the University of Maryland, College Park. She conducted post-doctoral research at NIH before transitioning to the technology transfer field in 2013.

## Daniel Reich, MD, PhD

Senior Investigator, Translational Neuroradiology Section, National Institute of Neurological Disorders and Stroke

*Moderator: How NIH Chooses What to Patent and License*

Dr. Daniel Reich is Senior Investigator at NIH/NINDS, where he directs the Translational Neuroradiology Section and leads clinical studies focusing on multiple sclerosis (MS). He studied math and physics at Yale and earned his MD from Cornell and his PhD in neurophysiology from The Rockefeller University. His training includes a fellowship in diagnostic neuroradiology and residencies in radiology and neurology at Johns Hopkins Hospital. He is a founder of the North American Imaging in MS Cooperative (NAIMS) and serves on the Board of Directors of the Americas Committee for Treatment and Research in MS (ACTRIMS). He is an elected member of the American Society of Clinical Investigation and the Association of American Physicians, the 2015 winner of the American Neurological Association's Derek Denny-Brown Young Neurological Scholar Award, the 2016 winner of the National MS Society's Barancik Award for Innovation in MS Research, and a 2017 winner of the NIH Graduate Partnership Programs Outstanding Mentor Award.

## Anthony Saleh, PhD

CEO, miRecule, Inc.

*Panelist: Perspectives from the Public and Private Sector*

Anthony is a biotech entrepreneur having founded and served in a variety of roles in several startup companies, including MIMETAS US, Birich Technologies, and Nitron Therapeutics. As an "Entrepreneur in Residence" at BioHealth Innovation, he has consulted for over a dozen biotech companies. In this role, he led technology diligence, market analysis and business and product development efforts. He also participated in funding raises for two companies, and performed scouting efforts for Roche and MedImmune, leading to several academic collaborations. As the President of MIMETAS US (an affiliate of the Dutch company Mimetas BV), he raised over $2.5 M in non-dilutive funding and over $1 M in commercial partnerships to develop organ-on-a-chip based drug discovery models. Dr. Saleh has more than 15 years of experience in microRNA research, nucleic acid chemistry and the design of therapeutic oligonucleotides at Johns Hopkins University, the National Institutes of Health, and in the private sector. Dr. Saleh is the lead inventor on miRecule's discovery platform.

## Michael Salgaller, PhD

Supervisory Technology Analysis and Marketing Specialist, National Cancer Institute

*Panelist: How NIH Identifies and Evaluates Licensees*

Michael Salgaller, PhD leads the Technology Analysis and Marketing Unit (TAMU) within the National Cancer Institute's Technology Transfer Center, where he leverages over 20 years of business, scientific, and investment experience in various life science sectors to support technology development and commercialization. The TAMU serves in a business development role to foster licensing and collaborative activity between buy-side stakeholders and the NCI (and NIH in general). He is a long-time industry executive who held various positions in boutique professional service and early-stage biotechnology firms. He also spent several years in government affairs and on the investment team of a venture capital firm dedicated to the life sciences. He is the author of "Biotechnology Entrepreneurship," and teaches an entrepreneurship class at NIH. He is on the Board of Canines-N-Kids, a foundation supporting cooperation between researchers in pediatric and veterinary oncology. He has written over 100 articles, presentations, and book chapters. Dr. Salgaller began his career as a Senior Scientist with NCI's Dr. Steve Rosenberg, after receiving his PhD in Pathology from The Ohio State University.

## Ameet Sarpatwari, PhD, JD

Assistant Professor of Medicine, Harvard Medical School; Assistant Director of the Program On Regulation, Therapeutics, And Law, Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women's Hospital

*Panelist: How NIH Negotiates License Terms*

Ameet Sarpatwari is an Assistant Professor of Medicine at Harvard Medical School, an Associate Epidemiologist at Brigham and Women's Hospital, and Assistant Director of the Program On Regulation, Therapeutics, And Law (PORTAL) within the Division of Pharmacoepidemiology and Pharmacoeconomics. His research draws upon his interdisciplinary training as an epidemiologist and lawyer and focuses on the effects of laws and regulations on therapeutic development, approval, use, and related public health outcomes. Among his scholarship, Dr. Sarpatwari has extensively evaluated the role of NIH in driving clinically meaningful innovation and accounting for public support of drug development.

Dr. Sarpatwari completed his undergraduate studies at the University of Virginia, where he was a Jefferson Scholar. He studied epidemiology at the University of Cambridge and subsequently studied law at the University of Maryland as a John L. Thomas Leadership Scholar. In addition to his role with PORTAL, Dr. Sarpatwari serves as a Faculty Affiliate with the Department of Health Policy and Management at the Harvard T.H. Chan School of Public Health, the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, the Behavioral Insights Group at the Harvard Kennedy School, and the Harvard-MIT Center for Regulatory Science. At the T.H. Chan School of Public Health, he is the Faculty Director of the JD/MPH program and teaches an annual course on public health law.

## Tara Schwetz, PhD

Acting Principal Deputy Director, NIH

Tara A. Schwetz, Ph.D., is the Acting Principal Deputy Director of the National Institutes of Health (NIH), effective December 20, 2021.

For much of 2021, Dr. Schwetz was on detail to the White House Office of Science and Technology Policy as the Assistant Director for Biomedical Science Initiatives. In this role, she led the efforts to stand up the Advanced Research Projects Agency for Health (ARPA-H). The Biden Administration has proposed ARPA-H to tackle some of the biggest health challenges facing Americans by driving medical innovation more rapidly.

Since 2019, Dr. Schwetz has served as the Associate Deputy Director of NIH and the Alternate Deputy Ethics Counselor for NIH. Throughout her more than 10-year tenure at NIH, Dr. Schwetz has held multiple positions across several Institutes and within the Office of the Director. She has served as the Acting Director and Acting Deputy Director of the National Institute of Nursing Research (NINR), the Chief of the Strategic Planning and Evaluation Branch at the National Institute of Allergy and Infectious Diseases, the Senior Advisor to the Principal Deputy Director of NIH, the NIH Environmental influences on Child Health Outcomes Interim Associate Program Director, and a Health Science Policy Analyst at the National Institute of Neurological Disorders and Stroke. Dr. Schwetz started her career at NIH as an AAAS Science and Technology Policy Fellow at NINR.

Dr. Schwetz has led or co-led a number of high-profile, NIH-wide efforts, including two Rapid Acceleration of Diagnostics programs (RADx Underserved Populations and RADx Radical), Implementing a Maternal health and Pregnancy Outcomes Vision for Everyone (IMPROVE) initiative, and NIH Presidential transition activities. She also has spearheaded several strategic planning efforts, such as the first NIH-Wide Strategic Plan, NIH-Wide COVID-19 Strategic Plan, NIAID Strategic Plan for Tuberculosis Research, NIH Office of the Director Strategic Engagement Agenda, and played a significant role in the development of the National Pain Strategy.

She received a B.S. in biochemistry with honors from Florida State University and a Ph.D. in biophysics from the University of South Florida, followed by a postdoctoral fellowship at Vanderbilt University.

## Laleh Shayesteh, PhD, JD

Director of Intellectual Property and Administration, Office of Technology Licensing, UC Berkeley
*Panelist: Perspectives from the Public and Private Sector*

Laleh is the Director of Intellectual Property and Administration in the Office of Technology Licensing where she develops UC Berkeley's IP strategy and oversees licensing for life sciences, chemistry, medical instruments, physical sciences, engineering, software technologies, and artificial intelligence. Laleh also handles trademark and copyright matters, and open source compliance. Additionally, she works with sister offices on IP matters for government grants and contracts, foundation grants and contracts, and sponsored research agreements.

Laleh is a trained scientist and worked for several years in research before practicing law. Prior to joining UC Berkeley, she performed population genetics research at Stanford, pediatric brain tumor research and ovarian cancer research at UCSF, brain tumor research at University of Chicago, and comparative genomics research at Exelixis. She then embarked on a law career and became a patent agent at Exelixis, followed by a director of IP and assistant general counsel for IP matters at SRI.

Laleh holds a Ph.D. in Biophysics from UC San Francisco and a J.D. from Concord Law School. She is a member of California State Bar and is also registered to practice before the US Patent and Trademark Office.

## Michael Shmilovich, JD

Senior Licensing and Patenting Manager, National Heart, Lung, and Blood Institute

*Panelist: How NIH Chooses What to Patent and License*

Michael “Misha” Shmilovich currently works as a senior licensing and patenting manager at NHLBI’s Office of Technology Transfer and Development. He has been with the NIH technology transfer program since early 2003. Misha has a B.S. in molecular biology and genetics from the University of Michigan, Ann Arbor. A law degree from American University and is a member of the bar in DC, California, and a registered patent attorney. He has completed graduate level course work in immunology through FAES. Misha also recently received an M.S. in medical cannabis science and therapeutics from the University of Maryland, School of Pharmacy.

## Courtney Silverthorn, PhD

Associate Vice President, Science Partnerships, Foundation for the National Institutes of Health
*Moderator: Perspectives from the Public and Private Sector*

Dr. Courtney Silverthorn is an Associate Vice President for Science Partnerships at the Foundation for the National Institutes of Health (FNIH). With extensive experience in public-private partnerships and federal technology transfer policy, she serves as the Director of the Accelerating Medicines Partnership® (AMP®) program and is responsible for new business development in platform approaches to therapeutics and the program's Bespoke Gene Therapy Consortium, a multi-year public-private partnership to advance manufacturing and regulatory frameworks for gene therapy treatments for rare diseases.

Prior to joining the FNIH, Courtney was the Acting Director of the Technology Partnerships Office at the National Institute of Standards and Technology (NIST), where she led technology transfer activities at the agency and was central to the interagency Lab-to-Market initiative. She also held tech transfer and policy roles at the Office of Science and Technology Policy, the Frederick National Laboratory for Cancer Research, and the National Cancer Institute.

Dr. Silverthorn earned a Ph.D. in Pharmacology from The Johns Hopkins University School of Medicine, a M.S. in Leadership from Washington University in St. Louis, and a B.S. in Biochemistry and Molecular Biology from Sweet Briar College.

## Surekha Vathyam, PhD

Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases

*Panelist: How NIH Chooses What to Patent and License*

Surekha Vathyam, Ph.D. serves as the Deputy Director of the Technology Transfer and Intellectual Property Office in the National Institute of Allergy and Infectious Diseases (NIAID) where she provides executive leadership for activities of a diverse staff engaged in implementing NIAID's technology transfer program. Previously, she was part of the leadership team at the National Cancer Institute's (NCI) Technology Transfer Center overseeing technology transfer operations. Before joining the NCI, she was a Senior Licensing and Patenting Manager at the National Institutes of Health (NIH) Office of Technology Transfer, where she evaluated, marketed, licensed and managed a wide range of NIH and FDA inventions and other intellectual property. Prior to her appointment at the NIH, she was a Patent Examiner at the US Patent and Trademark Office in the Chemistry Technology Center. Her professional experience also includes service as Director of the Research & Development and Director of Manufacturing divisions in a biotech company where she negotiated contracts and licenses, while developing medical diagnostics and therapeutics.

Dr. Vathyam earned her Ph.D. from The Johns Hopkins University in Biochemistry, where she performed NMR studies on iron containing superoxide dismutase. She received her M.Sc. in Chemistry from the Indian Institute of Technology, Madras, India and B.Sc. in Chemistry from Stella Maris College, Madras, India.

## Liza Vertinsky, PhD, JD

Professor of Law, University of Maryland Francis King Carey School of Law

*Panelist: How NIH Identifies and Evaluates Licensees*

Liza Vertinsky is a professor of law at the University of Maryland Francis King Carey School of Law, where she teaches and researches topics at the intersection of law, economics and social justice. She is a nationally recognized expert on the regulation of healthcare markets and emerging technologies, the role of public private collaborations in innovation and access to medicines.

Professor Vertinsky clerked for Judge Stanley Marcus, first for the U.S. District Court in the Southern District of Florida and then for the Eleventh Circuit Court of Appeals. She then practiced for a decade at two top law firms in the greater Boston entrepreneurial ecosystem, focusing on intellectual property transactions in the biomedical industry and university technology transfer. Professor Vertinsky joined the Emory Law School faculty in 2007, and the Maryland Carey Law faculty in July 2022. Her areas of expertise include the regulation of healthcare markets, the regulation of emerging technologies, AI and the law, global health law and policy, genetic privacy, intellectual property and innovation, and law and economics.

## Richard Wilder, JD

Professor of Practice, UNH Franklin Pierce School of Law; Senior Scholar, O'Neill Institute for National and Global Health Law, Georgetown University Law Center; Consultant & Strategic Advisor in Law and Global Health, Wilder Consulting LLC

*Panelist: How NIH Chooses What to Patent and License*

Richard Wilder is a senior scholar at the O'Neill Institute for National and Global Health Law.

Wilder is currently a professor of practice at the University of New Hampshire Franklin Pierce School of Law. Most recently, he served as general counsel and director of legal and business development at the Coalition for Epidemic Preparedness Innovations. There, he directed the legal and business development affairs of CEPI during its initial start-up phase and through the first two years of the response to the COVID-19 pandemic.

He previously had a similar role in the global health program at the Bill & Melinda Gates Foundation. Prior to that, he led the intellectual property policy team at the Microsoft Corporation where he was responsible for defining and driving the company-wide policy in all areas of intellectual property. Wilder has spent years as a partner in a global law firm, where he specialized in international trade law and practiced in the field of global public health. In this role, he advised the Global Fund to Fight AIDS, Tuberculosis, and Malaria; the World Health Organization; the Medicines for Malaria Venture; the Global Alliance for TB Drug Development; the U.S. Agency for International Development; and the Bill & Melinda Gates Foundation.

Wilder is a former director of the global intellectual property issues division of the World Intellectual Property Organization, a specialized agency of the United Nations in Geneva. He has also worked in private practice in the field of intellectual property and served as an attorney-advisor to the U.S. Patent & Trademark office addressing legislative and international affairs. He has taught many law courses at Georgetown University and the University of Malaya, Malaysia.

Wilder has an engineering degree from the University of Washington and practiced as a power generation engineer for several years before attending law school. He has a J.D. degree from the School of Law of the University of New Hampshire.