



**National Academy of Medicine Committee on Emerging Science,
Technology, and Innovation (CESTI)**

Virtual Workshop

April 14-15, 2022

Agenda and Background Information

**National Academy of Medicine Committee on Emerging Science,
Technology, and Innovation in health and medicine (CESTI)**
Virtual Workshop
April 14-15, 2022

Workshop Objectives

- Highlight existing health technology assessment models
- Explore public engagement models in health technology assessment, policymaking, and governance
- Discuss integration of guiding ethical principles into governance, including tools and frameworks to facilitate translation of guiding ethical principles into meaningful policy choices

April 14, 2022

11:00 – 11:25 am Welcome and Opening Remarks

Victor Dzau, President, National Academy of Medicine

CESTI Co-Chairs

Atul Butte, University of California, San Francisco

Alta Charo, University of Wisconsin, Madison

George Daley, Harvard Medical School

Consensus Study Co-Chairs

Keith Yamamoto, University of California, San Francisco

Keith Wailoo, Princeton University

11:25 – 11:45 am Keynote: Lessons Learned about Emerging Technology Governance

Gary Marchant, Arizona State University

11:45 – 12:15 pm CESTI Overview and Work to Date

Victor Dzau, President, National Academy of Medicine

Debra Mathews, Johns Hopkins

12:15 – 1:30 pm Session 1: Health Technology Assessment Models

Speakers

- Cinnamon Bloss, University of California, San Diego
- Tim Persons, Government Accountability Office
- Piers Millett, International Genetically Engineered Machine Foundation

Moderated Discussion

Moderator: Cara LaPointe, Johns Hopkins

1:30 – 1:45 pm Break

1:45 – 3:00 pm SESSION 2: Public Engagement Models

Speakers

- Debra Mathews, Johns Hopkins
- Mahmud Farooque, Arizona State University
- Jennifer Kuzma, NC State

Moderated Discussion

Moderator: Atul Butte, University of California, San Francisco

April 15, 2022

1:00 – 1:05 pm Welcome

Victor Dzau, President, National Academy of Medicine

1:05 – 2: 20 pm SESSION 3: Integration of Principles into Governance

Speakers:

- David Winickoff, Organisation for Economic Co-operation
- Jenny Reardon, University of California, Santa Cruz
- George Daley, Harvard Medical School

Moderated Discussion

Moderator: Alta Charo, University of Wisconsin, Madison

2:20 – 3:20 pm CESTI Straw Framework Elements & Heat Map

Debra Mathews, Johns Hopkins

Reactors

- Cathy Novelli, Georgetown University
- Kenneth Oye, MIT

3:20 – 3:30 pm Break

3:30 – 4:15 pm Moderated Discussion: Where do we go from here?

Reactors

- Elliott Chaikof, Beth Israel Deaconess Medical Center
- Juan Enriquez, Excel Venture Management
- Holly Fernandez Lynch, University of Pennsylvania

Moderated Discussion

Moderator: George Daley, Harvard Medical School

4:15 – 5:00 pm Consensus Study Statement of Task

Statement of Task

Consensus Study Co-Chairs

Keith Yamamoto, University of California, San Francisco

Keith Wailoo, Princeton University

Reflections from Sponsor Representatives

- Karen Cosby, Moore Foundation
- Michelle Groman, Greenwall Foundation
- Misti Ault Anderson, Greenwall Foundation
- Michelle Shevin, Ford Foundation on behalf of Public Interest Technology Infrastructure Fund
- John Smee, Qualcomm
- Lori Melichar, Robert Wood Johnson Foundation

5:00 pm Adjourn

Victor Dzau, President, National Academy of Medicine

Speaker and Moderator Bios

Misti Ault Anderson, MA, MS, is Program Director of The Greenwall Foundation. She is experienced in bioethics, science policy and education, and human research protections. She previously served as Senior Advisor for Public Health Education at the HHS Office for Human Research Protections and as Senior Policy and Research Analyst at the Presidential Commission for the Study of Bioethical Issues. At the Bioethics Commission, she served as staff lead for both bioethics education and for the Commission's work on neuroscience and ethics. Misti holds a BS in Microbiology from Clemson University, an MA in Science Education (chemistry) from UNC-Chapel Hill, and an MS in Biomedical Science Policy and Advocacy from Georgetown University.

Cinnamon S. Bloss, PhD, is a tenured Professor of Public Health, Psychiatry, and Medicine (Division of Biomedical Informatics) at the University of California San Diego. She is the Founding Director of the Center for Empathy and Technology, situated within the UCSD Institute for Empathy and Compassion, where she also serves as Associate Director. Dr. Bloss conducts interdisciplinary and transdisciplinary research focused on social and behavioral phenomena related to emerging information and biotechnologies. Her research is funded by the National Institutes of Health, the Defense Advanced Research Projects Agency, and philanthropic donations. Dr. Bloss was appointed by the NIH Director to serve as Chair of the Novel and Exceptional Technology and Research Advisory Committee, a federal advisory committee that provides recommendations to the NIH Director and a public forum for the discussion of scientific, safety, and ethical issues associated with emerging biotechnologies. Prior to assuming the chairpersonship of the committee, she served as Co-chair of the Gene Drives in Biomedical Research Working Group. Dr. Bloss has been recognized by the Western Societies of Medicine with the Carmel Prize for Research Excellence and has published over 100 papers and mentored over 50 trainees. She has received multiple teaching awards at UCSD, where she also founded a new concentration in Technology and Precision Health for the Master in Public Health degree. Dr. Bloss currently serves as Interim Assistant Dean of Academic Affairs in the Herbert Wertheim School of Public Health. She is a California-licensed clinical psychologist.

Atul Butte, MD, PhD, is the Priscilla Chan and Mark Zuckerberg Distinguished Professor and inaugural Director of the Bakar Computational Health Sciences Institute (bchsi.ucsf.edu) at the University of California, San Francisco (UCSF). Dr. Butte is also the Chief Data Scientist for the entire University of California Health System, with 17 health professional schools, 6 medical centers, and 10 hospitals. Dr. Butte has been continually funded by NIH for 20 years, is an inventor on 24 patents, and has authored over 200 publications, with research repeatedly featured in the New York Times, Wall Street Journal, and Wired Magazine. Dr. Butte was elected into the National Academy of Medicine in 2015, and in 2013, he was recognized by the Obama Administration as a White House Champion of Change in Open Science for promoting science through publicly available data. Dr. Butte is also a founder of three investor-backed data-driven companies: Personalis, providing medical genome sequencing services, Carmenta (acquired by Progenity), discovering diagnostics for pregnancy complications, and NuMedii, finding new uses for drugs through open molecular data. Dr. Butte trained in Computer Science at Brown University, worked as a software engineer at Apple and Microsoft, received his MD at Brown University, trained in Pediatrics and Pediatric Endocrinology at Children's Hospital Boston, then received his PhD from Harvard Medical School and MIT.

Elliot L. Chaikof, MD, PhD, is Chair of the Department of Surgery and Surgeon-in-Chief at the Beth Israel Deaconess Medical Center and Johnson and Johnson Professor of Surgery at Harvard Medical School. Dr. Chaikof is a member of Harvard Stem Cell Institute, the Wyss Institute of Biologically Inspired

Engineering of Harvard University, the Broad Institute and holds a faculty appointment at the Massachusetts Institute of Technology in the Harvard-MIT Division of Health Sciences and Technology. Dr. Chaikof received his B.A. and M.D. from Johns Hopkins University in Baltimore and his Ph.D. in Chemical Engineering from the Massachusetts Institute of Technology. He completed his training in General Surgery at the Massachusetts General Hospital and in Vascular Surgery at Emory University. His clinical interests focus on the treatment of vascular disease. He was among the core group of principal investigators that conducted the first FDA approved clinical trials of endovascular grafts for repair of aortic aneurysms and has been responsible for the formulation of clinical trial reporting standards and national best practice guidelines for the care of the patient with an aortic aneurysm. Dr. Chaikof's research interests lie at the interface of medicine and engineering with a focus on drug discovery and regenerative medicine. He has published more than 300 articles and his patents have been licensed to pharmaceutical and biotechnology companies. He is a scientific co-founder of Silicon Therapeutics, with support from Sequoia Capital, whose mission is the integration of computational methods and medicinal chemistry to address targets implicated in human disease. He was the recipient of the 2013 Clemson Award for Applied Research from the Society for Biomaterials and the 2019 Flance-Karl Award for seminal contributions in basic and translational research from the American Surgical Association. He currently serves as Chair for Section 1 and Co-Chair of the Health and Technology Interest Group of the National Academy of Medicine. He has also served on the National Academies' Review Panel of the Army Research Laboratory and is a member of the Biomedical Engineering Materials and Applications (BEMA) Committee of the National Academies.

R. Alta Charo, JD, is professor emerita of law and bioethics at the University of Wisconsin, and now works as an independent consultant to government and industry on medical and biotechnology ethics, policy and governance related to human therapeutics, agriculture, species conservation and national security. She was a member of President Clinton's National Bioethics Advisory Commission and worked as a legal and policy analyst for the former congressional Office of Technology Assessment, the US Agency for International Development and the FDA. Charo has been elected to the AAAS and the American Academy of Arts and Sciences, as well as the NAM. At the Academies, she was a member of the committee on science, technology and law (CSTL), and co-chaired the committee on guidelines for embryonic stem cell research, the committee on genome editing governance, and the committee on emerging science and technology innovation (CESTI). At present, she is a member of the Academies' committee on science, engineering, medicine, and public policy (COSEMPUP), and has consulting contracts with BioMADE, DARPA, Colossal, eGenesis, Vertex, Johnson & Johnson, and Gameto.

Karen Cosby, MD, FACEP, CPPS, is an academic emergency medicine physician who has practiced and taught emergency medicine for 30 years. She is currently a Program Director for the Diagnostic Excellence Initiative for the Gordon and Betty Moore Foundation where she leads a portfolio of grants for quality measure development and field building for diagnostic quality. As Associate Professor of Emergency Medicine at Rush University and senior emergency physician at Cook County Hospital she led departmental and hospital wide Quality and Oversight divisions and focused her academic work on better understanding medical error and finding system solutions to improve patient safety. She is one of the founding members of the Society to Improve Diagnosis in Medicine (SIDM) and helped originate and lead the SIDM Fellowship in Diagnosis. She is the author and editor of two books, *Patient Safety in Emergency Medicine*, and *Diagnosis: Interpreting the Shadows*.

George Q. Daley, MD, PhD, is the dean of Harvard Medical School. A world-renowned physician scientist and educator, his achievements span basic science, translational research and clinical medicine. Daley is at the forefront of stem cell science and cancer biology, and his discoveries have twice been cited in

Science's Top 10 Breakthroughs of the Year. His research paved the way for Gleevec, a “magic bullet” drug for chronic myeloid leukemia; generated stem cell models for more than a dozen human diseases; and advanced our understanding of tissue regeneration and bone marrow transplantation therapies. He has also been a central force in establishing international guidelines for the conduct of stem cell research. Daley earned his AB and MD degrees from Harvard and a PhD in biology from MIT, and has worked as a trainee, fellow and staff physician at several HMS-affiliated hospitals.

Victor J. Dzau, MD, is the President of the National Academy of Medicine (NAM), formerly the Institute of Medicine (IOM). In addition, he serves as Vice Chair of the National Research Council. Dr. Dzau is Chancellor Emeritus and James B. Duke Distinguished Professor of Medicine at Duke University and the past President and CEO of the Duke University Health System. Previously, Dr. Dzau was the Hershey Professor of Theory and Practice of Medicine and Chairman of Medicine at Harvard Medical School's Brigham and Women's Hospital, as well as Bloomfield Professor and Chairman of the Department of Medicine at Stanford University.

Dr. Dzau is an internationally acclaimed physician scientist and leader whose work has improved health and medicine in the United States and globally. His seminal work in cardiovascular medicine and genetics laid the foundation for the development of the class of lifesaving drugs known as ACE inhibitors, used globally to treat hypertension and heart failure. Dr. Dzau pioneered gene therapy for vascular disease and was the first to introduce DNA decoy molecules in humans in vivo. His pioneering research in cardiac regeneration led to the Paracrine Hypothesis of stem cell action and his recent strategy of direct cardiac reprogramming using microRNA. He maintains an active NIH-funded research laboratory.

Dr. Dzau is a leader in health and health policy. At the NAM, he has designed and led important initiatives such as the Commission on a Global Health Risk Framework for the Future; the Human Gene Editing Initiative; Vital Directions for Health and Health Care; and the Committee on Emerging Science, Technology, and Innovation in health and medicine.

He is active in advising science and health in US and globally. He has served as a member of the Advisory Committee to the Director of the National Institutes of Health (NIH), chaired the NIH Cardiovascular Disease Advisory Committee and NHLBI Cardiovascular Progenitor Cell Biology Consortium. Currently, he chairs the Cardiovascular Progenitor Cell Translational Consortium. He is a member of the Health and Biomedical Sciences International Advisory Council of Singapore, as well as a board member of the Imperial College Health Partners, UK and the Gairdner Foundation. He chairs the International Scientific Advisory Committee of the Qatar Precision Medicine Institute, the Scientific Boards of the Peter Munk Cardiac Center, University of Toronto and Institute of Cardiovascular and Medical Sciences, University of Glasgow. He served on the Board of Health Governors of the World Economic Forum.

Juan Enriquez, MBA, is managing director of Excel Venture Management, bestselling author and speaker. An investor in early stage private companies in the life sciences, brain, and big data sectors, Juan is one of the world's leading authorities on the uses and benefits of genomic code. He is the co-author of *Evolving Ourselves: Redesigning the Future of Humanity – One Gene at a Time* which describes a world where humans increasingly shape their environment, themselves, and other species. He is also the author of the global bestseller *As The Future Catches You* and of *The Untied States of America*, and co-author of *Homo Evolutis*. Juan writes, speaks, and teaches about the profound changes that genomics, brain technologies, and other life sciences will cause in business, technology, politics and society. He is one of the TED all-stars. He and Bill Gates were the first outside guest curators for TED. He

was the founding director of the Harvard Business School Life Sciences Project, is on the Harvard Medical School Advisory Council, and is a Research Affiliate in MIT's Synthetic Neurobiology Group. He serves on numerous Boards/Committees. He is a member of the American Academy of Arts & Sciences and the President's Council of the National Academy. He has published papers and articles in a wide variety of forums including The Harvard Business Review, Foreign Policy, Science, Nature, and the New York Times. He earned a BA and MBA from Harvard, with Honors.

Mahmud Farooque, PhD, focuses his work at ASU's Washington Center on linking science policy to better societal outcomes. His teaching, research and engagement are oriented towards making science more useful and democratic. He co-leads ASU Consortium for Science, Policy and Outcome's long-term efforts to build a community of practice among innovative R&D program managers in the government, non-government and private sectors. These include convening informal and formal knowledge exchanges between program managers about the challenges and opportunities for innovating in path dependent institutions.

Mahmud is the principal coordinator of Expert and Citizen Assessment of Science and Technology (ECAST) – a distributive institutional network that brings together research centers, informal science education centers, citizen science programs and non-partisan policy think tanks to engage citizens on decision-making related to science and technology policy. He led large-scale public participation projects on biodiversity, space, climate, and energy to support policy and decision-making at the national and global levels. His current public engagement projects involve Climate Change Resilience, Gene Drives, Driverless Cars, Geoengineering and Gene Editing.

Mahmud is editorial board member of TATuP – Journal for Technology Assessment in Theory and Practice (peer reviewed and open access) and advisory board member of ISE – Institute for a Sustainable Earth at George Mason University.

Mahmud was the Deputy Director of Policy Programs at the New York Academy of Science, Director of Collaborative Research at City University of New York, Associate Director for Research Development at Northwestern University, and Managing Director of USDOT Research Center at Purdue University.

Mahmud's expertise focuses on innovation systems, research management, knowledge co-production, policy entrepreneurship, and participatory technology assessment.

Michelle Groman, JD, is President & CEO of The Greenwall Foundation. She has wide-ranging experience in translating bioethics scholarship into real-world applications that affect everyday lives and draws on that experience to help realize the Foundation's vision of making bioethics integral to decisions in health care, policy, and research.

Michelle previously served as the Foundation's Chief Operating Officer (2018-2020) and Director of Bioethics Grants, Strategy, and Special Projects (2015-2017). Prior to joining the Foundation, Michelle was Associate Director at the Presidential Commission for the Study of Bioethical Issues where she oversaw work on diverse topics including neuroscience and related ethical issues, pediatric medical countermeasure research, and human subjects research protections.

A graduate of Harvard Law School, Michelle also practiced law in Washington, DC and clerked for the Honorable Bruce M. Selya on the U.S. Court of Appeals for the First Circuit. She has published articles on

various legal issues and topics in bioethics including end-of-life decision-making, research ethics, and emerging genetic technologies.

Jennifer Kuzma, PhD, is the Goodnight-NCGSK Foundation Distinguished Professor in the School of Public and International Affairs, and co-founder and co-director of the Genetic Engineering and Society (GES) Center (research.ncsu.edu/ges), at NC State University.

Prior to her current position, she was an associate professor at the Humphrey School of Public Affairs, University of Minnesota (2003-2013); study director at the National Academies of Science, Engineering, and Medicine (NASEM); and an AAAS Risk Policy Fellow at the USDA. She has over 150 scholarly publications on emerging technologies, their societal and ethical implications, and governance systems and has been studying these areas for over 25 years. Kuzma has held several national and international leadership positions, including a member of the World Economic Forum Council on Technology, Values and Policy; the NASEM Committee on Preparing for Future Biotechnology, Society for Risk Analysis (SRA) Council Member and Secretary, FAO Expert Group on Food and Nanotechnology, Council of Agricultural Science and Technology Committee on Gene Editing, and the AAAS-ABA National Council of Scientists and Lawyers. In 2014, she received the SRA Sigma Xi Distinguished Lecturer Award for her contributions to the field of risk analysis and in 2017-2018 she was awarded the Fulbright Canada Research Chair in Science Policy at UOttawa-ISSP. In 2019 she was elected a lifetime Fellow of AAAS for her distinguished work in anticipatory governance of new technologies, and methods for oversight policy analysis. She has given over 200 invited talks and is interviewed frequently in the media for her expertise in biotechnology policy, including the New York Times, Science, The Scientist, Nature, NPR, Washington Post, Scientific American, BBC, PBS Nova, Wired, and ABC & NBC News. Prior to becoming a social scientist and policy scholar, she earned her Ph.D. in biochemistry at UC-Boulder and did a postdoc in plant molecular biology at Rockefeller University.

Cara LaPointe, PhD, is a futurist who focuses on the intersection of technology, policy, ethics, and leadership. She works at the Johns Hopkins Applied Physics Laboratory where she serves as the Co-Director of the Johns Hopkins Institute for Assured Autonomy to ensure that autonomous systems are safe, secure, and trustworthy as they are increasingly integrated into every aspect of our lives. During more than two decades in the United States Navy, Dr. LaPointe held numerous roles in the areas of autonomous systems, acquisitions, ship design and production, naval force architecture, power and energy systems, and unmanned vehicle technology integration. At the Deep Submergence Lab of the Woods Hole Oceanographic Institution (WHOI), she conducted research in underwater autonomy and robotics, developing sensor fusion algorithms for deep-ocean autonomous underwater vehicle navigation. As a Senior Fellow at Georgetown University's Beeck Center for Social Impact + Innovation, she created the "Blockchain Ethical Design Framework" as a tool to drive social impact and ethics into blockchain technology. Cara holds a Doctor of Philosophy awarded jointly by the Massachusetts Institute of Technology (MIT) and WHOI, a Master of Science and a Naval Engineer degree from MIT, a Master of Philosophy from the University of Oxford, and a Bachelor of Science from the United States Naval Academy.

Gary Marchant, PhD, JD, MPP, is Regents' Professor and Faculty Director of the Center for Law, Science & Innovation at the Sandra Day O'Connor College of Law, Arizona State University (ASU). He also serves as a Professor at the School of Life Sciences and Distinguished Sustainability Scientist at the Global Institute of Sustainability at ASU. Professor Marchant's research interests include the governance of emerging technologies and the legal aspects of emerging technologies such as genomics, biotechnology, nanotechnology, artificial intelligence, neuroscience and blockchain. He teaches seven law school

courses each year including Law, Science & Technology; Artificial Intelligence & the Law; Genetics and the Law; Biotechnology: Science, Law and Policy; Health Care Technologies; Big Data, Privacy, and Emerging Technologies; and Blockchain and the Law.

Prior to joining ASU in 1999, Professor Marchant was a partner at the Washington, D.C., office of Kirkland & Ellis, where his practice focused on environmental and administrative law. During law school, he was Editor-in-Chief of the Harvard Journal of Law & Technology and editor of the Harvard Environmental Law Review, and was awarded the Fay Diploma (awarded to top graduating student at Harvard Law School). Professor Marchant frequently lectures about the intersection of law and science at national and international conferences. He has authored more than 150 articles and book chapters on various issues relating to emerging technologies. Among other activities, he has served on six National Academies of Science, Engineering and Medicine (NAEM) consensus committees, has been the principal investigator on several major grants, and has organized dozens of academic conferences and workshops on law and science issues including the annual Governance of Emerging Technologies and Science (GETS) conference. He has been elected a lifetime member of the American Law Institute and is a Fellow of the American Association for the Advancement of Science. He also chairs the IEEE Working Group (P2863) to create a governance standard for entities that develop or use artificial intelligence.

Debra JH Mathews, PhD, MA, is the Assistant Director for Science Programs for the Johns Hopkins Berman Institute of Bioethics, and an Associate Professor in the Department of Genetic Medicine, Johns Hopkins University School of Medicine. As the Assistant Director for Science Programs, Dr. Mathews is responsible for overseeing the Stem Cell Policy and Ethics program and the Program in Ethics and Brain Sciences, as well as other bench research-related endeavors in the Berman Institute. She also runs the Genomics and Society Mentorship Program and serves as the Chair of the Berman Institute's Inclusion, Diversity, Anti-Racism, and Equity (IDARE) Committee. Within the Institute for Assured Autonomy (IAA), Dr. Mathews serves as the Ethics & Governance Lead. In this role, she leads work focused on the ethical, societal, and governance implications of autonomous systems, and identifies opportunities across IAA for the integration of ethics and governance work and priorities.

Dr. Mathews's academic work focuses on ethics and policy issues raised by emerging technologies, with particular focus on genetics, stem cell science, neuroscience, synthetic biology, and artificial intelligence. Dr. Mathews is a member of the steering committee of The Hinxton Group, an international collective of scientists, ethicists, policymakers and others, interested in ethical and well-regulated science, and whose work focuses primarily on stem cell research. She has been an active member of the International Neuroethics Society since 2006 and has served on the Society's Board of Directors since 2015. In addition to her academic work, Dr. Mathews has spent time at the Genetics and Public Policy Center, the US Department of Health and Human Services, the Presidential Commission for the Study of Bioethical Issues, and the National Academy of Medicine working in various capacities on science policy.

Dr. Mathews earned her PhD in genetics from Case Western Reserve University, as well as a concurrent Master's in bioethics. She completed a Post-Doctoral Fellowship in genetics at Johns Hopkins, and the Greenwall Fellowship in Bioethics and Health Policy at Johns Hopkins and Georgetown Universities.

Lori Melichar, PhD, is a labor economist and the Senior Director of the Pioneer Portfolio at the Robert Wood Johnson Foundation, where she leads a team that is focused on discovering, exploring and learning from cutting edge ideas and emerging trends that have the potential to accelerate progress to create a Culture of Health in America. She is also the host of the Foundation's Pioneering Ideas podcast. Over the past 19 years, Melichar has created and managed several programs to focus a broad research

community on studies to improve health and healthcare policy and practice, and was a key driver of efforts to advance the science of quality improvement (QI) research and evaluation at the Foundation. From 2008-2010, she served as the Research Director for the Future of Nursing Committee, at the Institute of Medicine of the National Academy of Sciences. She holds a PhD and MA in economics from the University of Maryland at College Park and a BA in economics from Swarthmore College in Pennsylvania.

Piers Millett, PhD, is Vice President of the International Genetically Engineered Machine Foundation and a Senior Research Fellow at the Future of Humanity Institute, where he focuses on pandemic and deliberate disease and the implications of biotechnology.

Piers has consulted for the World Health Organization on research and development for public health emergencies. He spent more than a decade working for the Biological Weapons Convention, the international treaty that bans these weapons.

He has collaborated with a wide range of international organizations dealing with human and animal health, humanitarian emergencies and International Humanitarian Law, law enforcement, international security.

Piers holds advanced degrees in science policy, research methodology and international security. He has authored a wide range of policy, technical, and peer-reviewed documents across the full scope of health security and is a regular speaker at conferences, workshops and seminars around the world.

Piers also co-founded a successful consultancy firm that works with government, industry and academia to ensure the safe, secure and sustainable exploitation of biology as a manufacturing technology.

Ambassador Catherine A. Novelli, JD, LL.M., is a Senior Advisor at Shearwater Global, a strategic consulting firm. She also serves as President of Listening for America, a non-partisan, non-profit organization dedicated to forging a new vision of U.S. international trade engagement. She is an adjunct professor at Georgetown University, where she served as a Centennial Fellow (2018-2019). She previously served as Under Secretary of State for Economic Growth, Energy, and the Environment (2014-2017) where she promoted economic reform and open markets for U.S. products and services. Novelli spent seven years as Vice President, Worldwide Government Affairs at Apple Inc where she headed a multinational international team responsible for Apple's government relations and public policy. She had a long career at the Office of the U.S. Trade Representative, rising to Assistant U.S. Trade Representative for Europe & the Mediterranean, where she coordinated U.S. trade and investment policy for Europe, Russia, Central Asia, the Middle East and Northern Africa.

Novelli currently serves on the Board of the National Wildlife Federation, the Global Issues Advisory Board of the National Academy of Science, Engineering and Medicine and the Board of the Northern Virginia Community College. She is also on the Advisory Board of the Pristine Seas Initiative of the National Geographic Society.

Novelli has received numerous honors and awards, including the State Department Distinguished Service Award and the International Trade Woman of the Year Award. She is a graduate of Tufts University, holds a law degree from the University of Michigan and a Master of Laws from University of London.

Kenneth Oye, PhD, is a Professor of Political Science (School of Humanities Arts and Social Sciences) and Data Systems and Society (School of Engineering) and Director of the Program on Emerging Technologies (PoET), with work on international relations, political economy and technology policy. His work in international relations includes *Cooperation under Anarchy*, *Economic Discrimination and Political Exchange*, and four “*Eagle*” monographs on American foreign policy, and advisory work for the Petersen Institute, UNIDO and US Treasury, Commerce and EXIM. His work in technology policy has focused on adaptive management of risks associated with synthetic biology, pharmaceuticals, the internet and nuclear energy, with papers in *Nature*, *Science*, *Clinical Pharmacology and Therapeutics*, *Politics and the Life Sciences* and *Issues in Science and Technology*.

Professor Oye is a faculty affiliate of the MIT Synthetic Biology Center, the Center for Biomedical Innovation, and the Internet Policy Research Initiative. He chairs biosafety committees for iGEM and the Broad Institute Biofoundry and has served as an invited expert to the UN BWC, WHO, PCAST and NRC. He is a recipient of the Levitan Award for Excellence in Teaching (2011), the Graduate Council Teaching Award (1998) and the Technology and Policy Program Faculty Appreciation Award (2003). Before coming to MIT, Professor Oye taught at Harvard University, the University of California, Princeton University and Swarthmore College. He holds a BA in Economics and Political Science from Swarthmore College with Highest Honors and a Ph.D in Political Science from Harvard University with the Chase Dissertation Prize.

Timothy M. Persons, PhD, is the Chief Scientist and Managing Director of the Science, Technology Assessment, and Analytics team of the United States Government Accountability Office (GAO - the oversight, insight, and foresight entity of the U.S. Congress). In addition to founding GAO's Innovation Lab and leading advanced data analytic activities at GAO, he also directs GAO's science, technology, and engineering portfolio including technology assessment, technical assistance, and engineering sciences in support of the Congress and GAO. Prior to joining GAO, Dr. Persons served as the Technical Director for the Intelligence Advanced Research Projects Activity (IARPA) as well as the technical lead for Quantum Information Sciences and Biometrics research groups for the Information Assurance Directorate at the National Security Agency.

Jenny Reardon, PhD, is a Professor of Sociology and the Founding Director of the Science and Justice Research Center at the University of California, Santa Cruz. Her research draws into focus questions about identity, justice and democracy that are often silently embedded in scientific ideas and practices, particularly in modern genomic research. Her training spans molecular biology, the history of biology, science studies, feminist and critical race studies, and the sociology of science, technology and medicine. She is the author of *Race to the Finish: Identity and Governance in an Age of Genomics* (Princeton University Press, 2005) and *The Postgenomic Condition: Ethics, Justice, Knowledge After the Genome* (Chicago University Press, Fall 2017). She has been the recipient of fellowships and awards from, among others, the National Science Foundation, the Max Planck Institute, the Humboldt Foundation, the London School of Economics, the Westinghouse Science Talent Search, and the United States Congressional Committee on Science, Space and Technology. Recently, she started a project to bike over one thousand miles through her home state of Kansas to learn from farmers, ranchers and other denizens of the high plains about how best to know and care for the prairie.

Michelle Shevin, MA, is Senior Program Manager of the Public Interest Technology Catalyst Fund at the Ford Foundation. In the spirit of public interest law, the fund aims to build and sustain public-centered institutions, cross-sector career pathways for diverse technologists, and robust networks of aligned organizations expanding the space for justice and accountability. In her role, she manages a grantee portfolio within Ford Foundation as well as Ford's membership in cross-foundation initiatives including

the Public Interest Technology University Network and the Public Interest Technology Infrastructure Fund. Michelle also teaches critical futures thinking methodologies at NYU's Interactive Telecommunications Program.

John Smee, PhD, is Senior VP of Engineering and Head of Wireless Research at Qualcomm, where he oversees all 5G/6G and Wi-Fi R&D projects including systems design, standards contributions, and advanced radio, hardware, and software research testbeds and technology trials with industry partners. He joined Qualcomm in 2000, holds over 175 U.S. Patents, and has focused on the innovation and commercial launches of wireless communications across 5G NR, 4G LTE, 3G CDMA, and IEEE 802.11. He also leads Qualcomm's companywide academic collaboration program across technologies including wireless, semiconductor, automotive, multimedia, security, and machine learning. He received his Ph.D. in electrical engineering from Princeton University and holds an M.A. from Princeton and an M.Sc. and B.Sc. from Queen's University.

Keith Wailoo, PhD, is Henry Putnam University Professor of History and Public Affairs. He is jointly appointed in the Department of History and in the Princeton School of Public and International Affairs. Dr. Wailoo is former Vice Dean of the School of Public and International Affairs, former Chair of History, and current President of the American Association for the History of Medicine (2020-2022). His research straddles history and health policy, touching on drugs and drug policy, on the politics of race and health, on the interplay of identity, ethnicity, gender, and medicine, and on controversies in genetics and society. In 2021, Dr. Wailoo received the Dan David Prize for his "influential body of historical scholarship focused on race, science, and health equity; on the social implications of medical innovation; and on the politics of disease." His writings have advanced historical and public understanding on a range of topics: racial disparities in health care, the cultural politics of pain and opioids, how pandemic change societies, and the FDA's decision to ban menthol cigarettes. Before joining the Princeton faculty, Professor Wailoo taught in History and in Social Medicine (in the Medical School at UNC Chapel Hill), and at Rutgers University where he was Martin Luther King Jr. Professor of History and jointly affiliated with the History department and the Institute for Health, Health Care Policy, and Aging Research. He holds a Ph.D. in the History and Sociology of Science from the University of Pennsylvania, and a Bachelor's Degree in Chemical Engineering from Yale University. He was elected to the National Academy of Medicine and the American Academy of Arts and Sciences and is the recipient of numerous other academic honors.

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Keith Yamamoto, PhD, is University of California, San Francisco (UCSF) vice chancellor for science policy and strategy, director of precision medicine for UCSF, and professor of cellular and molecular pharmacology at UCSF. He is a leading researcher investigating transcriptional regulation by nuclear receptors, which mediate the actions of essential hormones and cellular signals; he uses mechanistic and systems approaches to pursue these problems in pure molecules, cells and whole organisms. He has led or served on numerous national committees focused on public and scientific policy, public understanding and support of biological research, and science education; he chairs the Coalition for the Life Sciences, and sits on the National Academy of Medicine Council and the National Academy of Sciences (NAS) Division of Earth and Life Studies Advisory Committee. As Chair of the NAS Board on Life Sciences, he created the study committee that produced “Toward Precision Medicine: Building a Knowledge Network for Biomedical Research and a New Taxonomy of Disease,” the report that enunciated the precision medicine concept, and he has helped to lead efforts in the White House, in Congress, in Sacramento and at UCSF to implement it. He has chaired or served on many committees that oversee training and the biomedical workforce, research funding, and the process of peer review and the policies that govern it at the National Institutes of Health. He is a member of the advisory board for Lawrence Berkeley National Laboratory and the board of directors of Research!America. He was elected to the National Academy of Sciences, the National Academy of Medicine, the American Academy of Arts and Sciences, and the American Academy of Microbiology, and is a fellow of the American Association for the Advancement of Science.

NATIONAL ACADEMY OF MEDICINE COMMITTEE ON EMERGING SCIENCE, TECHNOLOGY, AND INNOVATION

Overview

Advances in biomedical science, data science, engineering, and technology are leading to high-pace innovation with tremendous potential to transform health and medicine. At the same time, these innovations carry risks that have important implications for society related to access, cost, equity, social norms and ethics, and more. There is a need for society to understand the implications of such advances and to be prepared for them.

In 2018, the National Academy of Medicine (NAM) developed a 5-year strategic plan which explicitly identified health equity as a key priority. The strategic plan includes an important goal to provide leadership and engage broad communities in developing a framework to proactively address these impending challenges. To this end, the NAM has established the Committee on Emerging Science, Technology, and Innovation in health and medicine (CESTI).

Background and Context

The range of scientific and technological breakthroughs with transformative potential in health and medicine is extremely broad. Recent examples include: (1) Artificial intelligence (AI) in health care, such as AI-based clinical decision support, which could help improve medical diagnosis and treatment, but carries the risk of perpetuating inequity if, for example, the underlying data are biased; (2) Human genome editing technologies, especially CRISPR-Cas9, which have transformative and curative potential in medicine but also raise complicated questions around ethics, equity, fairness, and societal acceptance; and (3) New neural technologies, such as brain implants, which could be used to treat disorders such as Parkinson's disease, but could also be used to boost cognitive abilities, thereby raising significant ethical questions. Other breakthroughs with transformative potential and attendant risks include precision medicine, regenerative medicine, synthetic biology, organoids, and others.

Governance of emerging technologies often occurs in technology or sector-specific siloes. The successful development and adoption of new scientific knowledge and technologies will depend on an effective and enlightened health ecosystem that considers incentives, benefits, and risks across sectors at the outset. No single entity is capable of fully governing emerging technologies. CESTI is intended to provide an actionable solution to this problem, grounded in an understanding of how technologies emerge and the governance levers available to shape their growth and evolution.

Committee on Emerging, Science, Technology, and Innovation in Health and Medicine

CESTI brings together experts in diverse fields to assess the landscape of emerging scientific advances and technologies in health and medicine and address the potential societal, ethical,

legal, and workforce implications of such technologies, with the goal of developing a cross-sectoral governance framework. CESTI has engaged a remarkable number of experts representing perspectives from health, biomedical science, ethics, social sciences, law, regulation, industry, investment, and other disciplines. (Appendix A. CESTI Roster and Non-Member Experts) The diversity of perspectives across CESTI has led to rich discussions about emerging technology governance.

In order to meet its charge, CESTI worked diligently and undertook the following activities:

Case studies: CESTI developed a series of case studies representative of the landscape of emerging technologies and their potential societal, ethical, legal, and economic implications. Each case study focuses on a specific technology or set of recent technologies that continue to evolve, yet possess enough of a track record to enable the Committee to draw lessons from an existing evidence base.

Visioning: CESTI felt it was important to anticipate future challenges raised by emerging technologies in health and medicine. Therefore, the Committee added a visioning component to each case study to consider how a technology might evolve in the future and the societal implications of a particular evolutionary trajectory. These visioning exercises enable CESTI to consider additional complexity and pressure-test its early thinking about a framework for emerging technology governance (described below).

Principles and Commitments: In addition to the case studies and visioning exercises, CESTI articulated a set of normative and conceptual principles and commitments to guide the development of a governance framework. The principles and commitments are intended to remain relevant across sectors as new scientific and technological advances arise and as governance frameworks evolve. They capture 'higher-level' principles and values (e.g., justice and fairness) as well as 'process-level' commitments and specifications of principles (e.g., engagement with relevant communities).

Straw Governance Framework: To bring the case studies, visioning, and principles and commitments together, CESTI analyzed and synthesized lessons learned to develop a 'straw' governance framework, which will be presented for input and feedback in a public workshop in early 2022.

Public engagement: CESTI is currently surveying members of the general public about their experiences with and views of new technologies used in health and medicine (e.g., telemedicine, artificial intelligence, genome editing to treat disease). Survey results will be used to identify individuals interested in participating in a virtual listening session to further explore their experiences with and attitudes toward emerging technologies. In addition, survey results will inform the straw governance framework

Consensus Study

Building on the lessons learned and the straw framework proposed from the work of the first 2 years (2019-2021), the NAM will launch an in-depth consensus study in 2022 that will provide actionable guidance for the cross-sectoral governance of emerging technologies in health and medicine.

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Creating a Framework for Emerging Science, Technology, and Innovation in Health and Medicine

An ad hoc committee under the auspices of the National Academies of Sciences, Engineering, and Medicine will develop a governance framework for considering potential benefits and risks that emerging science, technology, and innovation in health and medicine can bring to society. The framework will be founded upon ethical principles with a focus on equity.

STATEMENT OF TASK

Building on the work of the National Academy of Medicine Committee on Emerging Science, Technology, and Innovation, a National Academies of Sciences, Engineering, and Medicine ad hoc committee will develop a cross-sectoral coordinated governance framework founded upon core ethical principles with a focus on equity, for considering the potential benefits and risks that emerging science, technology, and innovation in health and medicine can bring to society. The committee will:

1. Assess the existing ecosystem for cross-sectoral governance of emerging technologies in health and medicine with a focus on identifying governance gaps and unintended consequences raised by the current ecosystem;
2. Identify specific governance approaches at various points in the technology lifecycle to meaningfully translate key ethics principles into the governance ecosystem, with a particular focus on justice, equity and fairness;
3. Consider how to empower emerging technology stakeholders by aligning incentives to facilitate the development and use of transformative technologies while also mitigating potential risks and enhancing societal benefit; and
4. Recommend specific strategies and practical approaches to improve cross-sectoral and

coordinated governance of emerging technologies (e.g., forecasting mechanisms, coordination across sectors, principle-aligned governance levers, and public engagement) and to align governance with guiding ethics principles.

The committee's report will provide guidance for how to manage the risks, benefits, and ethical and societal implications of new technologies. While the committee will pay particular attention to the governance ecosystem in the United States, mechanisms to coordinate cross-border governance issues should also be considered where applicable.

STUDY SPONSORS

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COMMITTEE (Coming soon)**WEBSITE**

For additional information or to subscribe for periodic updates, please visit:
www.nationalacademies.org/our-work/creating-a-framework-for-emerging-science-technology-and-innovation-in-health-and-medicine

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