NATIONAL ACADEMIES Sciences Engineering Medicine

Sponsor Influences on the Quality and Independence of Health Research: A Workshop

Participant Biosketches

SESSION 1 – WELCOME, DO SPONSORING ORGANIZATIONS INFLUENCE RESEARCH?

LONNIE J. KING, THE OHIO STATE UNIVERSITY

Lonnie King, DVM, has more than 30 years of expertise in advancing the health and welfare of animals and humans. He is an innovator in veterinary education, biomedical research, and animal disease discovery. Dr. King is an expert in the "One Health" initiative and frequently serves as a keynote and guest panelist to diverse audiences worldwide regarding the convergence of human and animal health. He has also served as co-chair on the joint Task Force on Antibiotic Resistance in Production Agriculture to respond to the recommendations in the President's Council of Advisors on Science and Technology report on Antimicrobial Resistance. He is a member of the National Academy of Medicine. Dr. King earned a Doctor of Veterinary Medicine degree from The Ohio State University.

LISA BERO, UNIVERSITY OF COLORADO

Lisa Bero, PhD, is Chief Scientist, Center for Bioethics and Humanities and Professor of Medicine and Public Health at the University of Colorado (CU) Anschutz Medical Center and Senior Editor for Research Integrity for The Cochrane Collaboration. She is a leader in evidence synthesis, meta-research and studying commercial determinants of health, focusing on tobacco control, pharmaceutical policy, and public health. Dr. Bero has developed and validated qualitative and quantitative methods for assessing

bias in the design, conduct and dissemination of research and has pioneered the utilization of internal industry documents and transparency databases to understand corporate tactics and motives for influencing research evidence. She has authored academic articles with a focus on research integrity topics, including measuring problems with research integrity (methods issues, conflicts of interest, "spin"), testing methods to improve research integrity (training, policy development), and assessing how research is used or cited (in policy, media, or scientific literature). She has served on international committees for the National Academies of Sciences, Engineering, and Medicine, the International Agency for Research on Cancer (IARC), and the World Health Organization (WHO).

SESSION 2 – Protection of Research Integrity

Aaron Kesselheim, Harvard

Aaron Kesselheim, MD, JD, MPH, a Professor of Medicine at Harvard Medical School and a faculty member in the Division of Pharmacoepidemiology and Pharmacoeconomics in the Department of Medicine at Brigham and Women's Hospital (BWH). He also serves as a primary care physician at the Phyllis Jen Center for Primary Care at BWH. His research focuses on the effects of intellectual property laws and regulatory policies on pharmaceutical development, the drug approval process, and the costs, availability, and use of prescription drugs both domestically and in resource-poor settings. Within the Division, Dr. Kesselheim founded and leads the Program On Regulation, Therapeutics, And Law (PORTAL), an interdisciplinary research center focusing on intersections among prescription drugs and medical devices, patient health outcomes, and regulatory practices and the law. Kesselheim received his medical and legal training at the University of Pennsylvania and his MPH at the Harvard School of Public Health and is a member of the New York State Bar.

Patricia Valdez, National Institutes of Health

Dr. Patricia Valdez, PhD, is a Health Science Policy Analyst at the National Institutes of Health (NIH) and serves as the Extramural Research Integrity Officer in the NIH Office of Extramural Research (OER). In this position, she serves as a liaison between the NIH and the HHS Office of Research Integrity (ORI) and handles allegations of research misconduct in NIH-funded extramural activities. For the past two- and one-half years, she has been involved in the implementation of updates to NIH grant applications and review language aimed at enhancing the reproducibility of biomedical science through rigor and transparency. Prior to joining OER, Dr. Valdez served as the Manager of Publication Ethics for the American Society for Biochemistry and Molecular Biology (ASBMB). Dr. Valdez received her Ph.D. in Molecular and Cell Biology from the University of California, Berkeley.

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Daniel Greenbaum, Health effects Institute

Daniel Greenbaum is President of Health Effects Institute (HEI), where he leads HEI's efforts to provide public and private decision makers — in the U.S., Asia, Europe, and Africa — with high quality, impartial, relevant, and credible science about the health effects of air pollution to inform air quality decisions in the developed and developing world. In this role he works with HEI's sponsors in government and industry, its Scientific Committees and staff, and other environmental stakeholders to develop and implement the HEI Strategic Plan for Understanding the Health Effects of Air Pollution, which every five years sets HEI's course. Before coming to HEI, he served as Commissioner of the Massachusetts Department of Environmental Protection, where he was responsible for the Commonwealth's response to the Clean Air Act, as well as its award-winning efforts on pollution prevention, water pollution, and solid and hazardous waste. Mr. Greenbaum received his MS in city planning from the Massachusetts Institute of Technology.

Clive Green, AstraZeneca UK

Clive Green, PhD, is Executive Director of BioPharmaceuticals Research and Development at AstraZeneca where he leads research chemical synthesis using automated technologies and the global processing and distribution of research molecules. Dr. Green is also Chair of AstraZeneca's Governance Team for the Nagoya Protocol, which ensures the benefits from the utilization of non-human genetic resources (plant, animal, microbial or other origin containing functional units of heredity) are shared in a fair and equitable way; and Chair of AstraZeneca's Bioethics Advisory Group, which provides advice, support, and guidance to the company's scientists, project teams and leaders on bioethical issues. Dr. Green received his PhD from the University of Nottingham, UK.

Nicholas Chartres, University of California, San Francisco

Nicholas Chartres, PhD, is the Director of Science and Policy for the Program on Reproductive Health and the Environment (PRHE), which monitors and analyzes federal, state, and local chemical policy, including EPA's implementation of the Toxic Substances Control Act, the law that evaluates and regulates industrial chemicals used in U.S. commerce. He has extensive experience in the use of systematic review methods and leads PRHE's work in disseminating and implementing these methods to improve evidence evaluation in the environmental health sciences and ensure the best available science is used for policy decision making. As the lead author of the first in-depth study on how industry sponsorship influences nutrition research, he is an expert in identifying and analyzing industry influence and developing methods to reduce industry bias in the research process. In addition to his work at PRHE, Dr. Chartres is part of the World Health Organization/International Labor Organization (WHO/ILO) Joint Estimates Working Group examining global work-related burden of disease and injury. Dr. Chartres earned a PhD from the University of Sydney.

Gary Ruskin, U.S. Right To Know

Gary Ruskin is the executive director and co-founder of U.S. Right to Know. a nonprofit public interest investigative research group. He has co-authored 15 studies on corporate influence on research and health organizations, as well as corporate science denial, disinformation, and product defense. He previously directed the Congressional Accountability Project, which opposed corruption in the U.S. Congress. Mr. Ruskin earned a master's degree in public policy from Harvard.

SESSION 3 – Examples of Sponsor Influence of Health Research

Ross McKinney, Association of American Medical Colleges

Ross McKinney, MD, is the Chief Scientific Officer at the Association of American Medical Colleges (AAMC). He leads programs that support all aspects of medical research and training and represents the AAMC nationally on issues related to research and science policy, administration, workforce development, and education and training. Dr. McKinney joined the AAMC in 2016 after serving more than 30 years as a member of the Duke University faculty. During his time at Duke, he was director of the Division of Pediatric Infectious Diseases, vice dean for research at Duke University School of Medicine,

and director of the Trent Center for Bioethics, Humanities, and History of Medicine. Dr. McKinney earned an MD from Duke University.

David Michaels, George Washington University

David Michaels, PhD, MPH, is an epidemiologist and Professor at the Milken Institute School of Public Health at George Washington University. He served as U.S. Assistant Secretary of Labor for the Occupational Safety and Health Administration (OSHA) from 2009 to January 2017, the longest serving administrator in OSHA's history. During the Clinton Administration, Dr. Michaels served as US Assistant Secretary of Energy for Environment, Safety, and Health, charged with protecting the workers, community, and environment around the nation's nuclear weapons facilities. Much of his research focuses on protecting the integrity of the science underpinning public health, safety, and environmental protections. He is the author of The Triumph of Doubt: Dark Money and the Science of DECEPTION (Oxford University Press, 2020) and Doubt is Their Product: How Industry's Assault on Science Threatens Your Health (Oxford University Press, 2008). Dr. Michaels earned a PhD from Columbia University.

Adrian Hernandez, Duke

Adrian F. Hernandez, MD, is a cardiologist who serves as the Vice Dean for Clinical Research at the Duke University School of Medicine. Presently, he is the Coordinating Center Principal Investigator for PCORI's National Patient-Centered Clinical Research Network (PCORnet), NIH's Health System Collaboratory, and other pragmatic clinical trials to generate real world evidence. He is also the Coordinating Center Principal Investigator for the Baseline Health System Consortium which aims to change how clinical research is performed to integrate people in and outside of the health system, accelerate research, and improve efficiency. Dr. Hernandez's research focus is to improve population health, focusing on understanding health outcomes, and closing the gap between clinical efficacy and effectiveness. He is an expert in trial design, use of electronic health data, health services, regulatory science, and provided significant contributions in the fields of heart failure, outcomes research, population health, and clinical research methodology. He is an elected member of the American Society of Clinical Investigation and Association of American Physicians. Dr. Hernandez earned his medical degree from the University of Texas-Southwestern in Dallas.

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Laura Schmidt, University of California, San Francisco

Laura A. Schmidt, PhD, is a Professor of Health Policy in the School of Medicine at the University of California at San Francisco. She holds a joint appointment in the Philip R. Lee Institute for Health Policy Studies and the Department of Humanities and Social Sciences. Dr. Schmidt seeks to understand how changing lifestyles are contributing to rising rates of chronic disease across the globe and what to do about it. Her work explores the growing pressures of globalizing economies, rising inequality, and commercial products that undermine our health. She works directly with policymakers to craft and implement evidence-based policies that reduce the consumption of ultra-processed foods and other commercial products that harm human and planetary health. Dr. Schmidt received her PhD training in sociology at UC Berkeley and while there, also completed doctoral coursework in public health.

Martin McKee, London School of Hygiene and Tropical Medicine

Martin McKee, MD, is Professor of European Public Health at the London School of Hygiene and Tropical Medicine where he founded the European Centre on Health of Societies in Transition (ECOHOST), a WHO Collaborating Centre. He is also research director of the European Observatory on Health Systems and Policies and President of the European Public Health Association. He was elected to the UK Academy of Medical Sciences, the Romanian Academy of Medical Sciences, and the National Academy of Medicine. Dr. McKee was awarded honorary doctorates from Hungary, The Netherlands, and Sweden and visiting professorships at universities in Europe and Asia, the 2003 Andrija Stampar medal for contributions to European public health, in 2014 the Alwyn Smith Prize for outstanding contributions to the health of the population, and in 2015 the Donabedian International Award for contributions to quality of care. In 2005 was made a Commander of the Order of the British Empire (CBE). He received a medical degree from Queens University of Belfast, UK.

Adam Dunn, University of Sydney

Adam Dunn, PhD, is an Associate Professor in the Faculty of Medicine and Health and leads Biomedical Informatics and Digital Health at the University of Sydney. He works broadly across biomedical informatics using multidisciplinary tools and methods but most often in applications of machine learning and natural language processing. His key interests are in public health informatics, especially research about misinformation and health behaviors, and clinical research informatics, especially research about reducing bias and increasing timeliness of evidence synthesis from clinical trials. He has led or co-led research projects funded by the NHMRC, AHRQ, NLM/NIH, and WHO; the Convener of the Digital Health and Informatics Network at the University of Sydney; Affiliate Faculty with the Computational Health Informatics Program at Boston Children's Hospital; and has held editorial roles with a range of medical journals and computer science conferences. Dr. Dunn earned a PhD from the University of Western Australia.

Dean Schillinger, University of California, San Francisco

Dean Schillinger, MD, is a general internist, primary care physician and a University of California San Francisco (UCSF) Professor of Medicine. He is an international research expert in chronic disease-related public health, health communication, dissemination science and health policy. He recently completed a term as Chief of the Division of General Internal Medicine at San Francisco General Hospital and previously served as Chief of the Diabetes Prevention and Control Program for California. He co-directs an NIDDK-funded Center for Translational Research called DREAMS (DiabetesResearch forEquity through Advanced Multilevel Science). Of Chilean descent, he has extensive experience working with Latinx, Black, and Asian-Pacific Islander populations. He co-created a youth-led diabetes prevention social media campaign called The Bigger Picture, www.thebiggerpicture.org, which merges Arts with Public Health to catalyze social action; the campaign was recognized by the National Academy of Medicine and received WHO's Non-Communicable Disease Lab Award. Dr. Schillinger recently served as co-chair for a Congressionally charged federal diabetes commission that made transformative recommendations for an all-of-government approach to the epidemic. He received the American Public Health Association's Everett M. Rogers Award for lifetime achievement in health communication science and a WHO Non-Communicable Disease Policy award. Dr. Schillinger received a medical degree from the University of Pennsylvania.

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Cary Gross, Yale University

Cary Gross, MD, is a Professor of Medicine and Public Health, and Director of the National Clinician Scholars Program at Yale. His research addresses research integrity, as well as comparative effectiveness, quality, and health equity, with a focus on cancer prevention and treatment. He aims to use real-world research to generate knowledge that will inform change in clinical care and health policy. He is a founding Director of Yale's Cancer Outcomes Public Policy and Effectiveness Research Center (COPPER). In the realm of research integrity, Dr. Gross has investigated the relation between financial conflicts of interest and study outcomes, and ethical issues in disclosing financial ties to patients, as well as clinical trial data sharing. He earned his medical degree from New York University.

SESSION 4 – MODELS, PROCESSES, AND PRINCIPLES USED TO PROTECT THE INDEPENDENCE AND QUALITY OF RESEARCH

C.K. Gunsalus, National Center for Professional Research Ethics

C.K. Gunsalus, JD, is the Director of the National Center for Professional and Research Ethics (NCPRE), Professor Emerita of Business, and Research Professor at the Coordinated Sciences Laboratory. Gunsalus was the PI for the centerpiece project of NCPRE, Ethics CORE, a national online ethics resource center. She has been on the faculty of the colleges of Business, Law, and Medicine at the University of Illinois at Urbana-Champaign and served as Special Counsel in the Office of University Counsel. In the College of Business, she taught Leadership and Ethics in the MBA program and was the director of the required Professional Responsibility course for all undergraduates in the college. In Law, she taught Negotiation and Client Counseling; she was a member of the faculty of the Medical Humanities and Social Science program in the College of Medicine, where she taught communication, conflict resolution and ethics. Her experience at the University included technology transfer, management of conflicts of interest, human subject protection, and long-term service as the campus Research Standards Officer with responsibility for responding to allegations of professional misconduct by faculty and students. Ms. Gunsalus earned a JD from the University of Illinois.

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Sunita Sah, Cornell

Sunita Sah, MD, is a professor and organizational psychologist at Cornell University, director of Cornell's Academic Leadership Institute, and a Fellow at the University of Cambridge. Dr. Sah's research expertise is in conflicts of interest, disclosure, influence, professionalism, consent, compliance, and trust. She teaches leadership, negotiations, and critical thinking and she is currently on the scientific advisory board of the Behavioral Economics in Health Network, and the advisory board of the International Behavioral Public Policy Association, a fellow of the Society of Personality and Social Psychology, and on the editorial board of the journal, Behavioral Public Policy. Dr. Sah served as a Commissioner on the National Commission of Forensic Science and on the Human Factors Committee for the National Institute of Science and Technology Forensic Science Standards Board. Dr. Sah holds a PhD from Carnegie Mellon University and an M.B. Ch.B. (U.K. equivalent to the U.S. MD) from the University of Edinburgh.

Rita Redberg, University of California, San Francisco

Rita F. Redberg, MD, is a cardiologist and Professor of Medicine at the University of California, San Francisco, and Core Faculty at the Philip R Lee Institute for Health Policy Studies. She is the Chief Editor of JAMA Internal Medicine since 2009 and has spearheaded the journal's new focus on health care reform and "less is more". Her research interests are in health policy and technology assessment, and how to promote high value care, focusing on high-risk medical devices as well as the need for inclusion of women in clinical trials of such devices. Dr. Redberg served on the Medicare Payment Advisory Commission, which advises Congress on Medicare payment issues. She also served and chaired the Medicare Evidence, Development and Coverage Advisory Committee. She has given Congressional testimony multiple times in hearings related to the issue of balancing safety and innovation in medical device approvals. She worked in the office of Senator Hatch and with the Senate Judiciary Committee on FDA-related matters during her tenure as a Robert Wood Johnson Health Policy Fellow, 2003-2006. Dr. Redberg is a member of the National Academy of Medicine. She earned a medical degree from the University of Pennsylvania.

Quinn Grundy, University of Toronto

Quinn Grundy, PhD, RN, is Assistant Professor in the Lawrence S. Bloomberg Faculty of Nursing at the University of Toronto. Dr. Grundy's research explores the interactions between medically related industry and public health systems and the impacts on the delivery of health services, health evidence, and consumer health information. Dr. Grundy is the author of Infiltrating Healthcare: How Marketing Works Underground to Influence Nurses (Johns Hopkins University Press, 2018). She earned a PhD from the University of California, San Francisco.

Vincent Cogliano, California EPA Office of Environmental Health Hazard Assessment

Vincent Cogliano, PhD, has served since December 2019 as California Environmental Protection Agency's Office of Environmental Health Hazard Assessment's (OEHHA) Deputy Director for Scientific Programs. In this role, he manages OEHHA's scientific programs and essentially functions as the office's chief scientist. He brings to California more than 35 years of experience at federal and international health agencies in the assessment of environmental health risks. Prior to joining OEHHA, Dr. Cogliano worked for more than 25 years at the U.S. Environmental Protection Agency, where he directed its Integrated Risk Information System program, which identifies adverse health effects of chemicals in the environment and conducts analyses to support the protection of human health. He also served as deputy to the agency's scientific integrity official. His professional interests include qualitative and quantitative health risk assessment and its application to the protection of public health, especially in children and susceptible populations. Dr. Cogliano received his PhD from Cornell University.

Tracey Woodruff, University Of California, San Francisco

Tracey Woodruff, PhD, is a professor and director of UCSF Program on Reproductive Health and the Environment at the University of California, San Francisco. She is a leading scientist who has produced seminal research on how harmful chemicals and pollutants impact health, pregnancy, and child development, including the first international study to document the effects of air pollution and preterm birth and the first to document toxic chemicals in pregnant women and newborns. A national expert in chemical and regulatory policy, she was a senior scientist and policy advisor for the U.S. EPA's Office of Policy prior to joining UCSF. Dr. Woodruff earned a PhD from the University of California, San Francisco.

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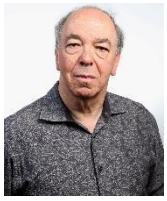

Joel Lexchin, York University in Toronto Canada

Joel Lexchin, MD, is a Professor Emeritus in the School of Health Policy and Management at York University in Toronto, Canada where he taught health policy until 2016. In addition, he worked in the emergency department at the University Health Network also in Toronto for over 33 years. He is the author or co-author of papers on a wide range of topics including drug regulation, pharmacosurveillance, drug promotion, research and development, access to medications in developing countries and physician prescribing behavior. He is a fellow of the Canadian Academy of Health Sciences and is among the top 2% of the world's most highly cited researchers. Dr. Lexchin received his MD from the University of Toronto.

Craig A. Umscheid, Agency for Healthcare Research and Quality

Craig A. Umscheid, MD, is a general internist and clinical epidemiologist who serves as the Director of the Evidence-based Practice Center Division and Senior Science Advisor at the Agency for Healthcare Research and Quality (AHRQ). He is also an Adjunct Professor of Medicine at Georgetown University School of Medicine, where he practices clinically. Prior to joining AHRQ, Dr. Umscheid was an associate professor at the University of Chicago, where he served as the chief quality and innovation officer and vice president of healthcare delivery science, with oversight of clinical quality, medical informatics, and clinical innovation. His career has been dedicated to developing, implementing, and evaluating approaches to integrate research evidence into practice across provider organizations in the pursuit of improving the quality and value of patient care. This work has been supported by AHRQ, the Patient Centered Outcomes Research Institute (PCORI), the Centers for Disease Control and Prevention (CDC), and the National Institutes of Health. Dr. Umscheid earned a medical degree from Georgetown University.