

Promoting Biomedical Innovation and Economic Value: New Models for Reimbursement and Evidence Development

Participant Biographies



Jerry Avorn, MD is professor of medicine at Harvard Medical School and chief of the Division of Pharmacoepidemiology and Pharmacoeconomics in the Department of Medicine at Brigham and Women's Hospital. An internist, geriatrician, and drug epidemiologist, he studies the intended and adverse effects of prescription drugs, physician prescribing practices, and medication policy. The division he founded and leads comprises physicians, epidemiologists, health policy analysts, statisticians, and computer scientists who work together to analyze the utilization and outcomes of prescription drugs in numerous settings. Dr. Avorn pioneered the "academic detailing" approach to continuing medical education, in which non-commercial, evidence-based information about drugs is provided to doctors through educational outreach programs run by public-sector sponsors. Such programs are now in use in the United States, Canada, Australia, and Europe. Dr. Avorn completed his undergraduate training at Columbia University in 1969, received the MD from Harvard Medical School in 1974, and completed a residency in internal medicine at the Beth Israel Hospital in Boston. He is a member of the Institute of Medicine Committee on Standards for Developing Trustworthy Clinical Practice Guidelines and is the author or co-author of over 275 papers in the medical literature on medication use and its outcomes, and of the book, *Powerful Medicines: The Benefits, Risks, and Costs of Prescription Drugs*, now in its 11th printing.



Robert Epstein, MD is Medco's president of advanced clinical science and research, and chief clinical research and development officer. Dr. Epstein is responsible for all of Medco's clinical research initiatives, including the Medco Research Institute™ and the United BioSource Research Divisions. In this role, Dr. Epstein oversees an extended research team that works to advance Medco's clinically ground-breaking and market-differentiating outcomes research initiatives. Additionally, Dr. Epstein is responsible for new and emerging clinical areas, including personalized medicine. Dr. Epstein is a trained epidemiologist, and worked in public health and academia before joining the private sector. He is past elected president of the International Society of Pharmacoeconomics and Outcomes Research, and has served on the board of directors for the Drug Information Association. He has published more than 50 peer-reviewed medical articles and book chapters, and serves as a reviewer for several influential medical journals.



Lou Garrison, PhD is professor in the Pharmaceutical Outcomes Research & Policy Program in the Department of Pharmacy and adjunct professor in the Departments of Global Health and Health Services at the University of Washington, where he joined the faculty in 2004. For the previous 12 years, he worked as an economist in the pharmaceutical industry. He was vice president and head of health economics & strategic pricing in Roche Pharmaceuticals, and was based in Basel, Switzerland, in 2002-2004. Prior to this, he was director of the Project HOPE Center for Health Affairs. In eight years there, he worked on a wide variety of health policy issues, including studies of health care reform both in the United States and overseas. Before this, he worked at the Battelle Human Affairs Research Centers in Seattle on studies of the adequacy of physician manpower supply and of the cost-effectiveness of kidney and heart transplantation. He received a BA in economics from Indiana University, and a PhD in economics from Stanford University. Dr. Garrison's research interests include national and international health policy issues related to personalized medicine, regulatory risk-benefit analysis, insurance, pricing, reimbursement, and risk-sharing agreements, as well as the economic evaluation of pharmaceuticals, diagnostics, devices, surgical procedures, and vaccines. From 2007-2009, he served on the board of directors of the International Society for Pharmacoeconomics and Outcomes Research.



Speaker Newt Gingrich is well-known as the architect of the “Contract with America” that led the Republican Party to victory in 1994. As an author, he has published twenty-two books, including 13 fiction and non-fiction *New York Times* best-sellers. Recent books include *Valley Forge* and *To Save America: Stopping Obama’s Secular-Socialist Machine*. He and his wife, Callista, host and produce historical and public policy documentaries. Recent films include *America at Risk*, *Nine Days that Changed the World*, *Ronald Reagan: Rendezvous with Destiny*, and *Rediscovering God in America*. Speaker Gingrich is founder of the Center for Health Transformation, general chairman of American Solutions for Winning the Future, a senior fellow at the American Enterprise Institute, a distinguished visiting scholar at the National Defense University, and honorary chairman of Renewing American Leadership.



Dana Goldman, PhD is the Norman Topping chair in medicine and public policy at the University of Southern California. Dr. Goldman is the author of over 100 articles and book chapters, and his research has been published in leading medical, economic, health policy, and statistics journals. He is a health policy advisor to the Congressional Budget Office, and serves on several editorial boards. Dr. Goldman's work has been featured in the *New York Times*, *Wall Street Journal*, *Washington Post*, *Business Week*, *U.S. News and World Report*, *The Economist*, NBC Nightly News, CNN, National Public Radio, and other media. In 2009, Dr. Goldman was elected a member of the Institute of Medicine in recognition of his professional achievement and commitment to service. He is also the 2009 recipient of the Eugene Garfield Economic Impact Prize, recognizing outstanding research demonstrating how medical research impacts the economy. He is a past recipient of the National Institute for Health Care Management Research Foundation award for excellence in health policy, and the Alice S. Hersh New Investigator Award recognizing contributions of a young scholar to the field of health services research. Dr. Goldman received his BA *summa cum laude* from Cornell University and a PhD in economics from Stanford University.



Scott Gottlieb, MD is a practicing physician and resident fellow at the American Enterprise Institute for Public Policy Research (AEI), a private, nonpartisan, not-for-profit institution dedicated to research and education on issues of government, economics, and social welfare. Previously, Dr. Gottlieb served the U.S. Food and Drug Administration (FDA) as deputy commissioner, senior advisor to the FDA commissioner, and director of medical policy development. He left FDA in the spring of 2004 to work on implementation of the new Medicare Drug Benefit, serving as a senior adviser to the administrator at the Centers for Medicare & Medicaid Services, where he supported the agency's policy work on quality improvement and coverage and payment decision-making, particularly related to new medical technologies.

Norma Holtz, RPh is the interim director of pharmacy at Health Alliance Medical Plans, Inc. At Health Alliance, she is dedicated to enhancing affordable quality pharmacy coverage for members participating in fully insured plans, self-funded plans, individual plans and plans for Medicare beneficiaries. Ms. Holtz assisted in the implementation of an innovative risk share agreement with the osteoporosis drug Actonel. In that agreement, the maker of Actonel agreed to reimburse Health Alliance for treatment of certain non-spinal osteoporotic fractures in women who adhered to the treatment regimen. Prior to her current role at Health Alliance, Ms. Holtz was a Branch Home Infusion Manager and Retail Manager. She has been a member of the Academy of Managed Care Pharmacy since 2006, and the Midwest Affiliate Chapter since its inception. She received her BS degree from the St. Louis College of Pharmacy.



Hervé Hoppenot is president of Novartis Oncology, where he leads the Global Oncology business unit, ranking second in the Global Oncology segment and supported by more than 6,000 employees in 50 countries. Novartis Oncology markets seven key products – Afinitor, Glivec, Femara, Zometa, Sandostatin LAR, Exjade and Tassigna – and has a leading pipeline in the industry. Prior to his role as president, Mr. Hoppenot served as chief commercial officer and head of Global Product Strategy & Scientific Development, overseeing medical affairs, global brand leadership, business development and licensing, health economics and pricing, early phase commercial development, strategic capabilities, and global sales excellence for Novartis Oncology. Mr. Hoppenot joined Novartis in 2003 as senior vice president, head of Global Marketing. Before joining Novartis, he served as vice president of oncology for Aventis where he led the Oncology Business Unit in the United States. Mr. Hoppenot holds an MBA from the ESSEC Business School.



Uday N. Kumar, MD, a cardiologist and cardiac electrophysiologist (EP) by training, is the founder and chief medical officer of iRhythm Technologies, Inc., a San Francisco-based medical device company focused on developing cost-effective new devices and systems for cardiac rhythm monitoring. He also currently is the fellowship director for Stanford University's Biodesign Global Programs (India and Singapore), programs that teach processes for medical innovation to help those countries solve their own unmet medical needs. Additionally, he is on the steering committee for Value-driven Engineering and U.S. Global Competitiveness, an initiative focused on developing policies and recommendations to promote and retain U.S. leadership in medical device development and innovation. He has served as an

adjunct clinical instructor of cardiovascular medicine and lecturer in bioengineering at Stanford, where he previously was a Biodesign Cardiovascular Innovation fellow. As a fellow, he focused on identifying and developing solutions to unmet needs in the field of cardiac EP; one of these ideas formed the basis for iRhythm Technologies, Inc. Prior to coming to Stanford, Dr. Kumar completed cardiac EP and cardiology fellowships at the University of California, San Francisco and training in internal medicine at Columbia-Presbyterian Hospital of Columbia University. Before his medical training, he helped launch Biomedical Modeling Inc., a company that created models from imaging data using rapid prototyping techniques for use in numerous medical applications. He received his MD and his BA in Biochemistry from Harvard University and grew up in Rhode Island.

Freda Lewis-Hall, MD, Pfizer's chief medical officer, leads Pfizer Medical, the division devoted to the safe, effective, and appropriate use of every Pfizer product, from its first use in a clinical trial until its last use anywhere in the world. She is a member of Pfizer's Executive Leadership Team and reports to Pfizer's president and chief executive officer, Ian Read. Prior to joining Pfizer, Dr. Lewis-Hall was a leader in medical affairs and biomedical product development with Vertex, Pharmacia, Bristol-Myers Squibb, and Eli Lilly. She also held leadership, medical and research positions at the National Institute of Mental Health and at the Howard University Hospital and College of Medicine. In September 2010, Dr. Lewis-Hall was appointed by the Obama Administration to the inaugural board of governors for the Patient-Centered Outcomes Research Institute, which will prioritize and direct a range of research programs to improve the nation's quality of health care. She also serves on the boards of the Institute of Medicine's Forum on Drug Discovery, Development, and Translation; the Foundation for the National Institutes of Health; the Harvard Medical School Board of Fellows; the Society for Women's Health Research; and the American Heart Association's "Power to End Stroke" initiative. She is a fellow of the New York Academy of Medicine and the American Psychiatric Association. Dr. Lewis-Hall received her BA from The Johns Hopkins University and her MD from Howard University College of Medicine.



Mark McClellan, MD, PhD is director of the Engelberg Center for Health Care Reform and Leonard D. Schaeffer Chair in Health Policy Studies at the Brookings Institution. At the Center, his work focuses on promoting high-quality, innovative and affordable health care. A doctor and economist by training, he also has a highly distinguished record in public service and in academic research. Dr. McClellan is a former administrator of the Centers for Medicare & Medicaid Services (CMS) and former commissioner of the Food and Drug Administration (FDA), where he developed and implemented major reforms in health policy. These include the Medicare prescription drug benefit, the FDA's Critical Path Initiative, and public-private initiatives to develop better information on the quality and cost of care. Dr.

McClellan chairs the FDA's Reagan-Udall Foundation, is co-chair of the Quality Alliance Steering Committee, sits on the National Quality Forum's Board of Directors, is a member of the Institute of Medicine, and is a research associate at the National Bureau of Economic Research. He previously served as a member of the President's Council of Economic Advisers and senior director for health care policy at the White House, and was an associate professor of economics and medicine at Stanford University.

Peter Orszag, PhD is vice chairman of global banking at Citigroup, Inc. and a member of the Senior Strategic Advisory Group there. He is also an adjunct senior fellow at the Council on Foreign Relations. Prior to joining Citigroup in January 2011, he served as a distinguished visiting fellow at the Council on Foreign Relations and a contributing columnist at the *New York Times*. Dr. Orszag previously served as the director of the Office of Management and Budget in the Obama Administration from January 2009 until July 2010. In that role, he oversaw the administration's budget policy, coordinated the implementation of major policy initiatives throughout the federal government, and reviewed federal regulatory action. From January 2007 to December 2008, Dr. Orszag was the director of the Congressional Budget Office (CBO). Under his leadership, the agency significantly expanded its focus on areas such as health care and climate change. Prior to CBO, Dr. Orszag was the Joseph A. Pechman senior fellow and deputy director of Economic Studies at the Brookings Institution. During the Clinton Administration, he was a special assistant to the president for economic policy. Dr. Orszag graduated *summa cum laude* in economics from Princeton University and obtained a PhD in economics from the London School of Economics, which he attended as a Marshall Scholar. He has coauthored or coedited a number of books, including *Protecting the Homeland* (2006), *Aging Gracefully: Ideas to Improve Retirement Security in America* (2006), *Saving Social Security: A Balanced Approach* (2004), and *American Economic Policy in the 1990s* (2002). He is a member of the Institute of Medicine, the Council on Foreign Relations, the Hamilton Project Advisory Council, the Marshall Scholarship Alumni Advisory Board, and Phi Beta Kappa.



Vicki L. Seyfert-Margolis, PhD is the senior advisor for science innovation and policy for the U.S. Food and Drug Administration's (FDA) Commissioner's Office. Dr. Seyfert-Margolis focuses on initiatives in innovation, regulatory science, personalized medicine and scientific computing and informatics. Previously, she served as chief scientific officer at Immune Tolerance Network (ITN), a non-profit consortium of researchers seeking new treatments for diseases of the immune system. At ITN, she oversaw the development of more than 20 centralized laboratory facilities, and the design and execution of biomarker discovery studies for over 25 Phase II clinical trials. As part of the biomarker efforts, she established construction of a primer library of 1,000 genes that may be involved in establishing and maintaining immunologic tolerance and co-

discovered genes that may mark kidney transplant tolerance. Dr. Seyfert-Margolis was also an adjunct associate professor within the department of medicine at the University of California, San Francisco. Prior to academia, she served as director of the Office of Innovative Scientific Research Technologies at the National Institute of Allergy and Infectious Diseases at the National Institutes of Health, where she worked to integrate emerging technologies into existing immunology and infectious disease programs. Dr. Seyfert-Margolis completed her PhD in immunology at the University of Pennsylvania's School of Medicine. She has co-authored numerous publications and has lectured internationally on various topics.



Steve Shak, MD has served as chief medical officer of Genomic Health since December 2000. From July 1996 to October 2000, Dr. Shak served in various roles in medical affairs at Genentech, Inc., most recently as senior director and staff clinical scientist. From November 1989 to July 1996, he served as a director of Discovery Research at Genentech, where he was responsible for pulmonary research, immunology and pathology. Dr. Shak led the clinical team that gained approval for Herceptin®, a targeted biologic treatment for breast cancer. He also initiated the cancer clinical trials of the anti-angiogenesis agent, anti-VEGF (Avastin®). In addition, Dr. Shak discovered Pulmozyme®, a mucus-dissolving enzyme that is approved worldwide for the treatment of the genetic disease cystic fibrosis. Prior to joining Genentech, Dr. Shak was an assistant professor of medicine and pharmacology at New York University School of Medicine. He holds a bachelor of arts degree in chemistry from Amherst College and an MD from New York University School of Medicine, and completed his post-doctoral training at University of California, San Francisco.



Reed V. Tuckson, MD, a graduate of Howard University, Georgetown University School of Medicine, and the Hospital of the University of Pennsylvania's General Internal Medicine residency and fellowship programs, is currently executive vice president and chief of medical affairs at UnitedHealth Group. As the most senior clinician of UnitedHealth Group, Dr. Tuckson is responsible for working with the company's diverse and comprehensive business units to improve the quality and efficiency of the health services provided to 75 million members worldwide. Formerly, Dr. Tuckson served as senior vice president, professional standards, for the American Medical Association. He is former president of the Charles R. Drew University of Medicine and Science in Los Angeles; has served as senior vice president for programs of the March of Dimes Birth Defects Foundation; and is a former commissioner of public health for the District of Columbia. Dr. Tuckson is an active member of the Institute of Medicine, and served as the chairperson of its Quality Chasm Summit Committee and a member on their Committee on the Consequences of the Uninsured. Recently, he was appointed to the National Institute of Health's Advisory Committee to the Director and the Department of Health and Human Services' Health Information Technology (HIT) Policy Committee – Enrollment Workgroup. He is past chair of the Secretary of Health and Human Services' Advisory Committee on Genetics, Health and Society. Additionally, he also served as a Commissioner, Certification Commission on Health Information Technology (CCHIT). Dr. Tuckson currently serves on the board of directors for several organizations including the Alliance for Health Reform; the American Telemedicine Association; the National Patient Advocate Foundation; Howard University; Big Brothers Big Sisters of the Greater Twin Cities; and Minnesota Public Radio. Dr. Tuckson has also held other federal appointments, including cabinet level advisory committees on health reform, infant mortality, children's health, violence, and radiation testing.



Sean Tunis, MD, MSc is the founder and director of the Center for Medical Technology Policy (CTMP). CTMP's main objective is to improve the quality and relevance of clinical research by providing a neutral forum for collaboration. Dr. Tunis was a member of the Institute of Medicine Committee on Initial National Priorities for Comparative Effectiveness Research. He advises a wide range of domestic and international public and private health care organizations on issues of comparative effectiveness, evidence-based medicine, clinical research, reimbursement, and health technology policy. Through September of 2005, Dr. Tunis was the director of the Office of Clinical Standards and Quality and chief medical officer at the Centers for Medicare & Medicaid Services (CMS). In this role, he had lead responsibility for clinical policy and quality for the Medicare and Medicaid programs. He also co-chaired the CMS Council on Technology and Innovation. Prior to joining CMS, Dr. Tunis was a senior research scientist with the Technology Assessment Group, the director of the health program at the Congressional Office of Technology Assessment, and a health policy advisor to the U.S. Senate Committee on Labor and Human

Resources. He received a BS degree in biology and history of science from the Cornell University School of Agriculture, and a medical degree and masters in health services research from the Stanford University School of Medicine. Dr. Tunis completed his residency training at UCLA and the University of Maryland in emergency medicine and internal medicine. He is board certified in internal medicine and holds adjunct faculty appointments at Johns Hopkins, Stanford, and the University of California San Francisco Schools of Medicine.