



Tomorrow's Doctors, Tomorrow's Cures®

FOCI Academe Meeting (Forum on Conflict of Interest in Academe)

**Hosted by Harvard University, Brigham and
Women's Hospital, Massachusetts General
Hospital, and Partners HealthCare**

June 28 - 30, 2009
The Fairmont Copley Plaza
Boston, Massachusetts

Association of
American Medical Colleges

FOCI Academe Meeting (Forum on Conflict of Interest in Academe)

**Hosted by Harvard University, Brigham and
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Agenda

Saturday, June 27

7:00 – 9:00 pm Pre-Meeting Steering Committee Dinner Commonwealth Room

Sunday, June 28

8:00 am – 12:00 pm Steering Committee Meeting Commonwealth Room

12:00 – 6:00 pm Registration/Information Outside Venetian Room

1:30 – 1:45 pm **Meeting Introduction** Oval Room

Ross McKinney, M.D., FOCI-A Chair

Director, Trent Center

Professor of Pediatrics, Molecular Genetics and Microbiology
Duke University School of Medicine

Barbara Bierer, M.D., FOCI-A Steering Committee

Meeting Host

Professor of Medicine, Harvard Medical School

Senior Vice President for Research

Brigham & Women's Hospital

Susan Ehringhaus, J.D.

Senior Director and Regulatory Counsel, Associate General Counsel

Association of American Medical Colleges

1:45 pm **Conflicts of Interest in Continuing Medical Education** Oval Room

1:45 – 2:00 pm

Framing the Issues

David Davis, M.D., F.C.F.P

Senior Director of Continuing Education and Performance
Improvement

Association of American Medical Colleges

2:00 – 2:50 pm

The ACCME Perspective and Audience Discussion

Murray Kopelow, M.D., M.S. (Comm), F.R.C.P.C.

Chief Executive Officer

Accreditation Council for Continuing Medical Education (ACCME)

Sunday, June 28 (continued)

2:50 – 3:30 pm	The Industry Perspectives and Audience Discussion Mike Saxton, M.Ed., F.A.C.M.E., C.C.M.E.P. Senior Director, Team Leader Medical Education Group Pfizer, Inc.	
3:30 – 3:45 pm	Break	<u>Venetian Room</u>
3:45 – 4:45 pm	Alternative Approaches and Audience Discussion Todd Dorman, M.D., F.C.C.M. Associate Dean and Director of Continuing Medical Education Johns Hopkins University School of Medicine Professor and Vice Chair for Critical Care Department of Anesthesiology and Critical Care Medicine Joint Appointments in Medicine, Surgery and the School of Nursing Johns Hopkins Medicine	
4:45 – 6:00 pm	Keynote Addresses Conflicts Beyond Compensation Steven E. Hyman, M.D. Provost, Harvard University Professor of Neurobiology, Harvard Medical School Ezekiel J. Emanuel, M.D., Ph.D. Chair, Clinical Center Department of Bioethics National Institutes of Health Special Advisor on Health Policy to the Director of the Office of Management and Budget	<u>Oval Room</u>
6:00 – 6:30 pm	Reception for attendees	<u>Ballroom Foyer</u>
6:30 – 8:30 pm	Dinner for attendees	<u>Grand Ballroom</u>

Monday, June 29

7:30 am – 5:30 pm	Registration/Information	<u>Venetian Room</u>
7:30 – 8:30 am	Networking Breakfast Table Discussions on Conflicts Topics	<u>Grand Ballroom</u>
8:30 – 8:40 am	Agenda for the Day Ross McKinney, M.D., FOCI-A Chair Director, Trent Center Professor of Pediatrics, Molecular Genetics and Microbiology Duke University School of Medicine	<u>Oval Room</u>
8:40 – 8:45 am	Welcome from Harvard Medical School Jeffrey Flier, M.D. Dean of the Faculty of Medicine Harvard Medical School	<u>Oval Room</u>
8:45 am	Conflicts of Interest in Clinical Care	<u>Oval Room</u>
8:45 – 9:00 am	Framing the Issues Joanne Conroy, M.D. Chief Health Care Officer Association of American Medical Colleges	
9:00 – 9:50 am	Perspectives from Academic Medicine Michael Cuffe, M.D. Vice President for Medical Affairs Duke University Health System Vice Dean for Clinical Affairs and Associate Professor of Medicine Duke University School of Medicine Michael J. Yaszemski, M.D., Ph.D. Professor of Orthopedic Surgery and Biomedical Engineering Mayo Clinic College of Medicine Consultant, Department of Orthopedic Surgery; Chair, Division of Spine Surgery Director, Tissue Engineering and Biomaterials Laboratory Departments of Orthopedic Surgery and of Physiology and Biomedical Engineering Mayo Clinic	

Monday, June 29 (continued)

9:50 – 10:30 am	Audience Discussion David Longnecker, M.D. Director, Health Care Affairs Association of American Medical Colleges	
10:30 – 10:45 am	Break	<u>Venetian Room</u>
10:45 am – 12:00 pm	Public Disclosure of Financial Ties Between Industry and Academia The Academic Perspective Guy Chisolm, III, Ph.D. Vice Chairman Lerner Research Institute Professor of Cell Biology Cleveland Clinic Foundation The Industry Perspective Cathryn M. Clary, M.D., M.B.A. Vice President, Medical Division Pfizer Inc.	<u>Oval Room</u>
12:00 – 1:15 pm	Networking Lunch	<u>Grand Ballroom</u>
1:15 – 1:30 pm	Break	<u>Venetian Room</u>
1:30 – 2:30 pm	Perspectives from NIH Sally Rockey, Ph.D. Acting Director for Extramural Research National Institutes of Health	<u>Oval Room</u>
2:30 pm	Institutional Conflicts of Interest	<u>Oval Room</u>
2:30 – 2:45 pm	Framing the Issues Karen Antman, M.D. Provost, Boston University Medical Campus Dean, School of Medicine Professor of Medicine	

Monday, June 29 (continued)

2:45 – 3:30 pm **The Optics of Institutional Conflicts of Interest**

Moderator:

Julie Gottlieb, M.A.

Assistant Dean, Policy Coordination

Johns Hopkins University School of Medicine

Speakers:

Patrick White, M.A.

Vice President for Federal Relations

Association of American Universities

Shannon Brownlee

Schwartz Senior Fellow

New America Foundation

3:30 – 3:45 pm Break

Venetian Room

3:45 – 4:05 pm **Lessons from Shepherding an ICOI Policy**

Speaker:

Ann Arvin, M.D.

Vice Provost and Dean of Research

Lucile Salter Packard Professor of Pediatrics and Professor of

Microbiology and Immunology

Stanford University

4:05 – 4:30 pm **Policy and Implementation Challenges and Audience Discussion**

Discussion Leaders:

Ross McKinney, M.D.

Director, Trent Center

Professor of Pediatrics, Molecular Genetics and Microbiology

Duke University School of Medicine

Patrick White, M.A.

Vice President for Federal Relations

Association of American Universities

Monday, June 29 (continued)

4:30 – 5:30 pm	Starting and Incubating Companies and Related Research The Partners Experience Christopher Colecchi, M.P.H. Vice President for Research Ventures and Licensing Partners HealthCare System, Inc. The UAB Experience Leona C. Fitzmaurice, Ph.D. Director, Technology Transfer The UAB Research Foundation The Mayo Clinic Experience Richard Ehman, M.D. Professor of Radiology Mayo Clinic	
5:30 – 5:45 pm	Break	
5:45 – 6:45 pm	Reception for attendees	<u>St. James/Singleton/Copley</u>
6:45 pm	Dinner on Your Own	

Tuesday, June 30

7:00 am – 12:30 pm	Registration/Information	<u>Venetian Room</u>
7:00 – 8:00 am	Networking Breakfast	<u>Grand Ballroom</u>
8:00 – 8:15 am	FOCI-A Business Meeting	<u>Oval Room</u>
	Ross McKinney, M.D., FOCI-A Chair Director, Trent Center Professor of Pediatrics, Molecular Genetics and Microbiology Duke University School of Medicine	
8:15 – 8:30 am	Update from the AAMC	<u>Oval Room</u>
	Susan Ehringhaus, J.D. Senior Director and Regulatory Counsel, Associate General Counsel Association of American Medical Colleges	
8:30 – 9:20 am	Lessons Learned from the Limelight and Audience Discussion	<u>Oval Room</u>
	Harry Greenberg, M.D. Senior Associate Dean for Research Joseph D. Grant Professor of Medicine and Microbiology & Immunology Stanford University School of Medicine	
9:20 am	Neglected COI Challenges in Research	<u>Oval Room</u>
9:20 – 9:35 am	Framing the Issues David Korn, M.D. Vice Provost for Research, Harvard University Professor of Pathology, Harvard Medical School	

Tuesday, June 30 (continued)

9:35 – 10:20 am	<p>Beyond Human Subjects Research</p> <p>What About Basic Research and its Intersection with Clinical Research? Allen Spiegel, M.D. The Marilyn and Stanley M. Katz Dean Albert Einstein College of Medicine Vice President of Medical Affairs Yeshiva University</p> <p>What About Engineering, Other Schools? Samuel L. Stanley, Jr., M.D. Professor of Medicine and Molecular Microbiology Washington University School of Medicine Vice Chancellor for Research Director, Midwest Regional Center of Excellence in Biodefense and Emerging Infectious Diseases (MRCE) Washington University in St. Louis</p>	
10:20 – 10:35 am	Break	<u>Venetian Room</u>
10:35 am	The Challenges of Accountability	<u>Oval Room</u>
10:35 – 10:45 am	<p>Framing the Issues Regina White, M.B.A. Associate Vice President, Research Administration Brown University</p>	
10:45 – 11:30 am	Breakout Sessions A, B and C	<u>Oval, St. James and State Suite A</u>
	<p>Breakout Session A: Development and Monitoring of COI Management Plans – Can We Assure Compliance?</p> <p>Discussion Leaders: Raymond Hutchinson, M.D., M.S. Associate Dean for Regulatory Affairs Professor of Pediatrics and Communicable Diseases University of Michigan Medical School</p> <p>Dana Burkley, M.H.A. Conflict of Interest Specialist University of Michigan Medical School</p>	<u>Oval Room</u>

Tuesday, June 30 (continued)

**Breakout Session B: Conflicts of
Commitment****St. James Room**

Discussion Leader:

Ross McKinney, M.D.

Director, Trent Center

Professor of Pediatrics, Molecular Genetics and Microbiology

Duke University School of Medicine

**Breakout Session C: The Challenges of
Pooled Industry Funding****State Suite A**

Discussion Leader:

Claudia Adkison, J.D., Ph.D.

Executive Associate Dean

Administration and Faculty Affairs

Emory University School of Medicine

11:30 am

**When Do We Say “No” to COIs – Open Discussion
of Results of Survey of Meeting Participants****Oval Room**

11:30 – 11:50 am

Presentation of Survey Results**Julie Gottlieb, M.A.**

Assistant Dean, Policy Coordination

Johns Hopkins University School of Medicine

Guy Chisolm, III, Ph.D.

Vice Chairman

Lerner Research Institute

Professor of Cell Biology

Cleveland Clinic Foundation

11:50 am – 12:20 pm **Audience Discussion**

Discussion Leader:

Marianne Hockema, M.A.

Administrator

Office of COI Review

Mayo Clinic

Tuesday, June 30 (continued)

12:20 – 12:30 pm

Closing Remarks

Oval Room

Ross McKinney, M.D., FOCI-A Chair

Director, Trent Center

Professor of Pediatrics, Molecular Genetics and Microbiology

Duke University School of Medicine

Barbara Bierer, M.D., FOCI-A Steering Committee

Meeting Host

Professor of Medicine, Harvard Medical School

Senior Vice President for Research

Brigham & Women's Hospital

Speaker Biographical Sketches

Claudia R. Adkison, J.D., Ph.D., has been executive associate dean, administration and faculty affairs, and professor of cell biology at Emory University School of Medicine since 1995. She functions as chief operating officer, academic affairs facilitator, and faculty dean in the medical school. Reporting to the dean, Dr. Adkison has day-to-day oversight responsibility for administration; faculty affairs (appointments, promotions, development, and problems); legal and many regulatory matters for the medical school; conflict of interest and academic misconduct; arrangements and problem-solving for academic programs; special projects and problems with the medical school chairs, university administrators, and various school and university administrative units; and a wide variety of special projects for the dean involving both academic and clinical areas. She also developed and conducts a “chair school” for all new medical school department chairs at Emory.

Prior to her present position, Dr. Adkison was a faculty member in Emory School of Medicine for many years. During the end of that period, she also acquired a law degree (at night) that led her to leave Emory for a few years to practice intellectual property law as a biotech patent attorney with numerous medical school and biotech clients, as a copyright litigator, and also as a health care lawyer in the international law firm Kilpatrick & Stockton. Her J.D. degree is from Georgia State University College of Law, where she served on law review while she carried out her full-time duties as a professor, educator, and scientist in Emory Medical School’s Department of Cell Biology, chaired the University Senate and Research Committee, and served on numerous school and university committees. She is a member of the State Bar of Georgia and the U.S. Patent and Trademark Bar, in addition to numerous medical school, university, and professional society committees. Dr. Adkison received her Ph.D. degree from Tulane University and completed postdoctoral fellowship training in cell biophysics at Baylor College of Medicine. She is currently serving as the first national chair of the new Association of American Medical Colleges Forum on Conflict of Interest.

Karen Antman, M.D., who is recognized internationally as an expert on breast cancer and other malignancies, assumed the positions of provost of the medical campus and dean of Boston University School of Medicine in May 2005. Dr. Antman came to Boston University from the National Cancer Institute of the National Institutes of Health (NIH) where she served as deputy director for translational and clinical sciences in 2004 and 2005. Previously, she spent more than 10 years on the faculty of Columbia University College of Physicians and Surgeons, where she was Wu Professor of Medicine and Pharmacology and director of the Herbert Irving Comprehensive Cancer Center, a National Cancer Institute-designated Cancer Center. Dr. Antman was voted Senior Faculty Teacher of the Year by medical residents at Columbia in 1993. She also served on the faculty of Harvard Medical School from 1979 to 1993, and had hospital appointments at Brigham and Women’s Hospital and Dana-Farber Cancer Institute in Boston and Presbyterian Hospital in New York.

Best known among oncologists for developing a standard treatment regimen for sarcomas, as well as her team's research on blood growth factors, Dr. Antman also is outspoken on public health policy issues. She has written extensively about impediments to clinical research on cancer, and she has testified before Congress on the need for federal research dollars to support cancer research with articles in the medical literature (as well as *Vogue* and *Readers Digest*). She has written more than 300 journal papers and edited five textbooks and monographs, many with multiple editions.

Dr. Antman has served as president of the American Society of Clinical Oncology, the American Association for Cancer Research, and the American Society for Blood and Marrow Transplantation. She served for seven years as an associate editor of the *New England Journal of Medicine* and currently serves on the international editorial board of the *Lancet* and several other major medical journals. She currently sits on the council of the NIH's Fogarty International Center.

Ann Arvin, M.D., is the Lucile Salter Packard Professor of Pediatrics and professor of microbiology and immunology, Stanford University School of Medicine, and serves as the vice provost and dean of research, Stanford University.

Dr. Arvin is a graduate of Brown University (A.B., magna cum laude), earned an M.A. degree in philosophy at Brandeis, and received her M.D. degree from the University of Pennsylvania in 1972. She completed her pediatrics residency at the University of California-San Francisco and subspecialty training in infectious diseases at UCSF and Stanford. Her principal research interests are the human herpesviruses and childhood viral diseases and vaccines. Her basic laboratory research focuses on varicella zoster virus (VZV), a herpesvirus that causes chicken pox and herpes zoster (shingles). She has done extensive basic work on the molecular mechanisms of VZV pathogenesis and how the host immune system controls VZV infections, and did early studies of varicella-zoster virus vaccine that is now licensed for the prevention of chickenpox and zoster. Her clinical research uses new laboratory methods to better understand the developing immune system in infants and young children and how maturation of the immune system affects responses to viral infections and vaccines.

Dr. Arvin was elected to the Institute of Medicine of the National Academy of Science in 2003. She has received the E. Mead Johnson Award for Research in Pediatrics, the John Enders Award in Medical Virology, the Albion Walter Hewlett Award, Stanford University School of Medicine and other awards. In recognition of her contributions to basic and clinical research, she has been named a fellow of the American Pediatric Society, the Infectious Diseases Society of America, and the Association of American Physicians. At present, she serves on the board on life sciences, National Academy of Science/National Research Council and the director's advisory council of the National Institutes of Health National Institute of Allergy and Infectious Diseases.

Dr. Arvin has been appointed to many national committees, including the FDA Vaccines and Related Biologics Products Advisory Committee, Howard Hughes Research Training Fellowships Review Committee, Council of the American Society of Virology, Basic Science Advisory Committee for the March of Dimes Birth Defects Foundation, Executive Committee, NIH Collaborative Antiviral Study Group, the Thrasher Foundation Advisory Board and the National Vaccine Advisory Committee (advisory to the Secretary of the Department of Health and Human Services), and was chair of the WHO Committee on Research Related to Measles and Measles Vaccine.

Dr. Arvin served as chief of the infectious diseases division, department of pediatrics, Stanford University School of Medicine, and the Lucile Packard Children's Hospital at Stanford from 1984 to 2006. She was associate dean of research at Stanford University from 2001 to 2006.

Barbara E. Bierer, M.D., is senior vice president for research at the Brigham and Women's Hospital and professor of medicine at Harvard Medical School. Dr. Bierer, a graduate of Harvard Medical School, completed her internal medicine residency at the Massachusetts General Hospital and her hematology and medical oncology training at the Brigham and Women's Hospital and the Dana-Farber Cancer Institute. Dr. Bierer maintained a research laboratory in the department of pediatric oncology at Dana-Farber Cancer Institute and was appointed director of pediatric stem cell transplantation at Dana-Farber Cancer Institute and Children's Hospital in 1993. In 1997, she was named chief of the Laboratory of Lymphocyte Biology at the National Heart, Lung, and Blood Institute (NHLBI) at the National Institutes of Health in Bethesda, Md. She served on the scholars committee of the Howard Hughes Medical Institute and on the admissions committee of the Biomedical Research Training Program for Underrepresented Minorities at NHLBI, where she received its Director's Award in 1999. She returned to the Dana-Farber Cancer Institute in July 2002, as vice president of patient safety and director of the Center for Patient Safety. In 2003, Dr. Bierer moved to the Brigham and Women's Hospital to assume her current position. In addition, in 2006, Dr. Bierer established the Center for Faculty Development and Diversity at the Brigham and Women's Hospital and now serves as its first director. For these efforts, she was the first recipient of the Harvard Medical School Harold Amos Faculty Diversity Award in 2008.

Dr. Bierer's laboratory research interests include mechanisms of T cell activation and of immunosuppression, interests that complement her clinical commitment to hematology. In addition to her academic responsibilities, Dr. Bierer was elected to, and continues on, the board of directors of the Association for Accreditation of Human Research Protection Programs (AAHRPP), serving as its president from 2003 to 2007 and was on the board of directors of the Federation of American Societies for Experimental Biology. She was a member of the medical and scientific advisory board and, later, the board of directors of ViaCell, Inc. She is on the editorial boards of a number of journals including *Current Protocols of Immunology*, *Journal of Immunology*, and *Blood*. She is currently a member of the AAMC-AAU Advisory Committee on Financial Conflicts of Interest in Clinical Research; on the National Academies of Sciences Committee on Science, Technology, and the Law; and on the Secretary's Advisory Committee for Human Research Protections, for which she serves as chair.

Dr. Bierer lives with her husband, Steven Hyman, and their three children. Her hobbies include reading memos.

Shannon Brownlee is a nationally known writer and essayist whose work has appeared in such publications as the *Atlantic Monthly*, *New York Times Magazine*, *The New Republic*, *Slate*, *Time*, the *Washington Post*, and the British medical journal *BMJ*. Her book, *Overtreated: Why Too Much Medicine is Making Us Sicker and Poorer*, was named the best economics book of 2007 by *New York Times* economics correspondent David Leonhardt.

A former senior writer at *U.S. News & World Report*, Brownlee is now a Woodrow Wilson Visiting Scholar and a Senior Fellow at the New America Foundation, a non-partisan think tank in Washington, DC. Her work focuses on issues surrounding health care policy, the pharmaceutical industry, and the nature of evidence in medicine. She lectures regularly at universities, medical schools, and in public venues, and is the recipient of numerous journalism awards. She holds a master's degree in marine science from the University of California, Santa Cruz and is a member of the Association of Health Care Journalists, the American Society of Journalists and Authors, and the National Association of Science Writers. She lives on the Chesapeake Bay with her husband and son.

Six years ago, Brownlee became interested in the question of why the United States has the most expensive health care in the world but some of the worst health statistics among developed nations. At 17 percent of GDP, the U.S. spends more per capita than any other developed country, yet we rank near the bottom in such key health statistics as infant mortality, rates of medical errors, and longevity. Her reporting led her to write *Overtreated*, a well-documented and engaging exploration of the links between the high cost of American medicine, its poor quality, and unnecessary care -- which accounts for as much as a third of every health care dollar spent. In her book, Brownlee makes the case for changing the way doctors and hospitals are paid, and the way medicine is organized as necessary antidotes for poor quality and high costs.

Dana Burkley, M.H.A., is manager of the conflict of interest office at the University of Michigan Medical School. She has been a health care administrator for the past 25 years, working in a variety of capacities in both the private and the public sectors. Ms. Burkley served as a senior planning manager at the Christ Hospital in Cincinnati, Ohio, and at Community General Hospital in Syracuse, N.Y., after which she became an operations manager for Health Services Association, also in New York. She joined the health information technology consulting firm Vector Research (now Altarum, Inc.) in 1996, managing private, state, and federal contracts. Prior to her work with the conflict of interest office, Ms. Burkley served as a manager in the University of Michigan School of Public Health. Her current responsibilities include management of the Medical School Research Conflict of Interest Board, Clinical Conflict of Interest Group, outside interest disclosure system, and conflict of interest policy development.

Guy M. Chisolm III, Ph.D., is vice chair of the Lerner Research Institute and professor of cell biology at Cleveland Clinic. He holds secondary professorships in the Cleveland Clinic Lerner College of Medicine (CCLCM) of Case Western Reserve University, Kent State University, and Cleveland State University. He received his bachelor's degree from the University of Pennsylvania, his Ph.D. degree from the University of Virginia, and postdoctoral research training from the Karolinska Institute (Stockholm) and Massachusetts Institute of Technology. He has published more than 110 scientific articles, most on the cell biology of atherosclerosis. His research funding has come predominantly from multiple grants from the National Institutes of Health (NIH), but also the American Heart Association (AHA) and the pharmaceutical industry. He received the Research Merit Award from the American Heart Association's Ohio Valley Affiliate (2001) and a Special Recognition Award for Vascular Biology Research from the AHA's (national) Council on Arteriosclerosis, Thrombosis and Vascular Biology (2006). He has served on editorial boards for journals and multiple grant review study sections for the NIH and AHA. He has served on Cleveland Clinic's board of governors and board of trustees. He is heavily involved in the newly created Cleveland Clinic Lerner College of Medicine of Case Western Reserve University. He is co-director of the school's basic science curriculum and sits on the admissions, faculty appointments and promotions, student promotion, and GI curriculum committees. He received the 2007 Lerner Research Institute Award for Excellence in Education. Dr. Chisolm is also director of Cleveland Clinic's Innovation Management and Conflict of Interest Program, chair of its IM&CoI Committee, a member of the clinic's board of trustees CoI Committee, and helped craft the clinic's current conflict of interest policies. He is a member of Case Western Reserve University's CoI Committee and their President's Committee on CoI Policy Development. He is on the steering committee for the AAMC (Association of American Medical Colleges) Forum on Conflict of Interest in Academe, hosted their annual national meeting (September 2006), and served on the planning committees for their annual meetings sponsored by Johns Hopkins (September 2007), Mayo Clinic (September 2008), and Partners (Boston, June 2009). He was a member of the joint AAMC-AAU Advisory Committee on Conflicts of Interest in Human Subjects Research (2007-2008).

Cathryn Clary, M.D., M.B.A., is a vice president in the medical division of Pfizer Inc. Her recent responsibilities have encompassed oversight of strategies and partnerships with external medical customers in the United States, as well as leading many of Pfizer's recent policy changes related to transparency and disclosure. Her previous responsibilities included management of the Phase IV U.S.-based clinical and outcomes research activities supporting the Pfizer portfolio, as well as oversight of the field-based medical, medical information, customer medical, medical education (CME), and regulatory groups supporting Pfizer medicines in the United States. In addition, she has run a task force at Pfizer responsible for defining and communicating the optimal policies on conflict of interest for an ethical pharmaceutical company.

Before joining Pfizer, Dr. Clary practiced psychiatry for 13 years, was engaged in psychiatric administration of both the private and not-for-profit sectors, and ran a clinical research site affiliated with the University of Pennsylvania. Her work has been published in multiple peer-reviewed journals.

Dr. Clary received her medical degree at the University of Missouri–Columbia in 1979, and completed a residency in psychiatry at the Hospital of the University of Pennsylvania, in 1983, receiving the Laughlin Award for outstanding psychiatric resident. She completed a master’s degree in business administration at the University of Delaware in 1996. She is a distinguished fellow of the American Psychiatric Foundation.

Christopher H. Colecchi is vice president for research ventures and licensing at Partners Healthcare--an integrated health system founded in 1994 by the Harvard-affiliated Brigham and Women’s Hospital and Massachusetts General Hospital.

Mr. Colecchi leads business development, technology transfer, and commercialization activities at Partners and oversees efforts to establish strategic alliances with the life sciences industries. He is also responsible for the Partners Innovation Fund--an internal venture capital fund that makes investments in early stage science from Partners hospitals to create start-up companies to improve patient care.

Previously, Mr. Colecchi was director of clinical trials and industrial relations for Massachusetts General Hospital. Earlier in his career, he served as director of clinical monitoring for a clinical research organization at which he oversaw the set-up and management of multi-center, industry-sponsored clinical trials at several hundred sites throughout the United States and Canada. Within that role, he worked directly with most of the major international pharmaceutical and biotechnology companies as well as many in the device arena.

Mr. Colecchi is a current board member of both the Harvard Clinical Research Institute and the Massachusetts Association for Mental Health. He is an advisor to Broadview Ventures--the venture capital arm of the Paris-based Leducq Family Trust--which has as its goal the acceleration of advances in cardiovascular disease through the support of early stage technology ventures. He is also a member of the 2009 Boston Executive Leadership Institute sponsored by the MIT Sloan School of Management and the Greater Boston Chamber of Commerce.

Mr. Colecchi previously served on the boards of directors of the Massachusetts Biotechnology Council and the Starlight Children’s Foundation. He was also a member of the advisory board for the Warwick Business School studying Biomedical Innovation across the United Kingdom and United States. He holds a B.A. degree from Holy Cross College and M.P.H. degree from the University of Massachusetts School of Public Health.

Joanne M. Conroy, M.D., as chief health care officer at the AAMC (Association of American Medical Colleges), focuses on the interface between the health care delivery system and academic medicine, paying particular attention to how health care in academic settings can address quality-of-care and patient-centered care issues. Dr. Conroy represents the interests of approximately 400 major teaching hospitals and health systems, including 64 Veterans Affairs medical centers, through the AAMC Council of Teaching Hospitals and Health Systems, in addition to overseeing the Group on Faculty Practice, Group on Resident Affairs, Chief Medical Officers Group, and the Compliance Officers Forum.

Dr. Conroy came to the association after serving as executive vice president of Atlantic Health System and chief operating officer of Morristown Memorial Hospital in Morristown, N.J. In those roles, Dr. Conroy gained an understanding of health system operations, hospital-physician relationships, and collaborative partnerships among the various elements of academic health systems. Dr. Conroy earned her B.A. degree in chemistry from Dartmouth College and was awarded her M.D. degree from the Medical University of South Carolina.

Michael S. Cuffe, M.D. was appointed vice president for medical affairs at Duke University Health System in 2005. In this position, Dr. Cuffe leads efforts to enhance physician relations and improve the quality of care and overall patient experience at the Duke University Health System. He also leads initiatives to improve patient safety, including the implementation of the ambulatory medical record. In addition to this position, Dr. Cuffe was recently appointed (spring 2008) as vice dean of medical affairs for the Duke School of Medicine. In this role, Dr. Cuffe oversees continuing and graduate medical education, as well as clinical department and faculty reviews and strategy.

Prior to his appointments, Dr. Cuffe served as vice chair for clinical affairs of the department of medicine, Duke University Medical Center. From 1997 to 2000, Dr. Cuffe served as director of the Duke Clinical Research Institute's Site Management and Clinical Monitoring section.

Dr. Cuffe is a graduate of Massachusetts Institute of Technology and received his medical degree from Duke University School of Medicine, where he also completed an internal medicine internship, cardiology fellowship, and served as chief resident. While a house officer, Dr. Cuffe was elected to Alpha Omega Alpha and was a Joseph C. Greenfield Scholar. His research pursuits include management of acute and chronic congestive heart failure, evaluation of alternative medicine practices, and depression as related to cardiovascular disease. Dr. Cuffe's interests include general and preventive cardiology, heart failure, vascular disease, patient safety, quality assurance, and sports medicine. He is an associate professor of medicine in the division of cardiology, Duke University Medical Center. Dr. Cuffe is currently completing his master's degree in business administration at the Duke University Fuqua School of Business.

Dave Davis, M.D., C.C.F.P., F.C.F.P., F.R.C.P.C. (hon.), senior director, continuing education and performance improvement, at the AAMC (Association of American Medical Colleges) in Washington, D.C. He was previously adjunct professor, department of health policy, management, and evaluation, University of Toronto; and department of family and community medicine, University of Toronto.

Currently the AAMC's lead for continuing health care education and improvement, Dr. Davis was a family physician in Ontario, Canada, for nearly 40 years. For much of that time, he was active in continuing medical education (CME) as chair of an all-staff interprofessional continuing education program at a community hospital; director of continuing medical education and subsequently chair of continuing education at McMaster University's Faculty of Health Sciences; associate dean, continuing education, and founding director of the Knowledge Translation Program in the faculty of medicine, University of Toronto; and chair of Ontario's Guidelines Advisory Committee.

Dr. Davis has also developed a comprehensive competency assessment program for the provincial licensing body, and helped launch a center for faculty development and a Mini-Med School at the University of Toronto. Emphasizing a rigorous, outcomes-based focus on CME, he has acted as principal investigator, co-principal investigator, or investigator on grants totaling several million dollars. This emphasis has seen the publication of over 100 peer-reviewed papers, dozens of abstracts, book chapters, and two major books on CME practices and presentations on four continents. His (and colleagues') 1995 JAMA systematic review of the effect of CME interventions is widely cited as a seminal study in this field. Finally, Dr. Davis has been chair or president of national or provincial Canadian organizations; two North American organizations (the Alliance for CME and the Society for Academic CME); and the Guidelines International Network, a global organization dedicated to the development and implementation of evidence-based clinical practice guidelines.

Todd Dorman, M.D., is associate dean and director of continuing medical education for the Johns Hopkins University School of Medicine (JHUSOM) in Baltimore, Md. He is a professor and vice chair of the department of anesthesiology/critical care medicine at JHUSOM. He has joint appointments as a professor in the departments of medicine and surgery as well as the Johns Hopkins School of Nursing.

Dr. Dorman earned his medical degree at Tulane University School of Medicine in New Orleans. He completed his internship and residency in internal medicine at Charlotte Memorial Hospital and Medical Center in North Carolina. He then completed a residency in anesthesiology/critical care medicine and a fellowship in critical care medicine at Johns Hopkins Hospital. He remains board-certified in internal medicine and anesthesiology and has special qualifications in critical care medicine. Dr. Dorman has authored and coauthored over 100 peer-reviewed journal articles, chapters, and books. He is also on the editorial boards of prominent journals, including *Critical Care Medicine* and the *Journal of Continuing Education in the Health Professions* and serves as a journal reviewer for other journals. He is president of the American Society for Critical Care Anesthesiologists (ASCCA), president-elect for the Society for Academic CME (SACME), and a member of Council for the Society of Critical Care Medicine (SCCM). Dr. Dorman has also lectured internationally on management of the critically ill and organizational management for ICUs and nationally on conflict of interest, and CME as a value center. He is the recipient of several awards and honors including the Fox Award for Research in CME.

Dr. Dorman recently served as co-principal investigator for the AHRQ-funded project on the effectiveness of CME, which published its findings in monograph form in January 2007. He serves on the ACCP Guidelines Panel for the Guidelines on CME. Dr. Dorman also served on the Institute of Medicine Committee on Conflict of Interest in Education, Research, and Practice that released its report in April 2009. He also serves on the Physician Accountability for Physician Competency group.

Dr. Dorman serves as the co-chair of the Johns Hopkins Committee on Conflict of Interest and recently helped spearhead an updated policy across Hopkins Medicine regarding interactions with industry and a new policy on speaker's bureau participation. He also serves on the Institutional Conflict of Commitment Committee.

Dr. Richard Ehman is professor of radiology at the Mayo Clinic and serves on the Mayo Clinic board of governors and the Mayo Clinic board of trustees. His main clinical activity is magnetic resonance imaging. His research program is focused on developing new imaging technologies. He received his M.D. degree from the *University of Saskatchewan, Canada*, in 1979, completed residency training in diagnostic radiology at the *University of Calgary* in 1983, and then undertook a research fellowship at the *University of California, San Francisco*. He joined the Mayo Clinic staff in 1985.

Dr. Ehman has been principal investigator of several National Institute of Health (NIH) grants and holds more than 30 U.S. and foreign patents for his inventions. He was awarded the Gold Medal of the *International Society for Magnetic Resonance in Medicine* in 1995 for his research contributions, an honorary doctor of science degree by the *University of Saskatchewan* in 2000, and the Outstanding Researcher Award of the *Radiological Society of North America* in 2006.

Dr. Ehman has served as chair of the *Radiology and Nuclear Medicine Study Section* of the NIH, and is currently a member of the advisory council of the *National Institute of Biomedical Imaging and Bioengineering* of the NIH. He is an associate editor of *Magnetic Resonance in Medicine*, and a member of the editorial boards of several other journals. He served as president of the *International Society for Magnetic Resonance in Medicine* in 2002-2003.

Susan H. Ehringhaus, J.D., is senior director, regulatory counsel, and associate general counsel at the AAMC (Association of American Medical Colleges). Prior to coming to the AAMC, she was vice chancellor and general counsel and adjunct professor of law at the University of North Carolina at Chapel Hill, where she served as the university's senior legal counsel for 29 years. During her years at the AAMC, she has also served as an adjunct professor of law at Georgetown Law Center.

Ms. Ehringhaus joined the AAMC in January 2003 where her work focuses generally on health law and specifically includes legal, ethical, and business issues in biomedical research and conflicts of interest in all areas of academic medicine. She has been throughout her career actively involved in legal and policy matters relating to higher education, including health law, technology transfer, research issues, conflicts of interest, finance, business, corporate affiliations, as well as other areas in higher education. She taught the law of higher education at the University of North Carolina School of Law for many years as well as other courses, and she has also taught the law of higher education at Georgetown University's Law School. She has been a key participant in the development of U.S. standards for addressing conflicts of interest in academic medicine and has spoken widely about the subject. Her recent publications have focused on integrity and conflicts of interest in clinical research and in academic medicine generally.

Ms. Ehringhaus has served as a lecturer and consultant to many organizations on various legal issues in scientific research, medical education, and higher education, and she has received several honors and awards.

Ezekiel J. Emanuel, M.D., Ph.D., is an internationally known bioethicist and a breast oncologist. He is the Chair of the Clinical Center Department of Bioethics at the National Institutes of Health but currently serving as a Special Advisor on Health Policy to the Director of the Office of Management and Budget.

After completing Amherst College, he received his M.Sc. from Oxford University in Biochemistry. He received his M.D. from Harvard Medical School and his Ph.D. in political philosophy from Harvard University. His dissertation received the Toppin Award for the finest political science dissertation of the year. In 1987-88, he was a fellow in the Program in Ethics and the Professions at the Kennedy School of Government at Harvard.

After completing his internship and residency in internal medicine at Boston's Beth Israel Hospital and his oncology fellowship at the Dana-Farber Cancer Institute, he joined the faculty at the Dana-Farber Cancer Institute and was an Associate Professor at Harvard Medical School.

Dr. Emanuel has authored 3 books and co-edited 4. Publications include The Oxford Textbook of Clinical Research Ethics, edited by Dr. Emanuel and members of the NIH Department of Bioethics and Healthcare, Guaranteed, Dr. Emanuel's own recommendations for health care reform and, just published by Princeton University Press, Exploitation and Developing Countries. His book on medical ethics, The Ends of Human Life, has been widely praised and received honorable mention for the Rosenhaupt Memorial Book Award by the Woodrow Wilson Foundation. Dr. Emanuel has also published No Margin, No Mission: Health-Care Organizations and the Quest for Ethical Excellence and co-edited Ethical and Regulatory Aspects of Clinical Research: Readings and Commentary.

Dr. Emanuel developed The Medical Directive, a comprehensive living will that has been endorsed by *Consumer Reports on Health*, *Harvard Health Letter*, the *New York Times*, *Wall Street Journal*, and many other publications. He has published widely on the ethics of clinical research, health care reform, international research ethics, end of life care issues, euthanasia, the ethics of managed care, and the physician-patient relationship in the *New England Journal of Medicine*, *The Lancet*, *JAMA*, and many other medical journals.

He has received numerous awards including the election to the Association of American Physicians, the AMA-Burroughs Wellcome Leadership Award, the Public Service Award from the American Society of Clinical Oncology, the 2nd Annual John Mendelsohn Award from the MD Anderson Cancer Center, and a Fulbright Scholarship (which he declined). In 2004, Dr. Emanuel was elected to membership in the Institute of Medicine (IOM) of the National Academy of Science. In 2007, Roosevelt University presented Dr. Emanuel with the President's Medal for Social Justice.

Dr. Emanuel served on President Clinton's Health Care Task Force, the National Bioethics Advisory Commission (NBAC), and on the bioethics panel of the Pan-American Healthcare Organization. Dr. Emanuel has been a visiting professor at the University of Pittsburgh School of Medicine and the Brin Professor at Johns Hopkins Medical School.

Dr. Leona C. Fitzmaurice is director of technology transfer for the UAB Research Foundation (UABRF) at the University of Alabama in Birmingham (UAB). Dr. Fitzmaurice joined UABRF in October 2004. She previously served as executive director of the Washington State University (WSU) Research Foundation; in this capacity, she also directed Washington State University's Office of Intellectual Property Administration and the WSU Research Park. Prior to her time in Washington, she was assistant director and then associate director for life sciences in the University of Florida's Office of Technology Licensing. Dr. Fitzmaurice has facilitated the patenting, marketing, and licensing of numerous technologies and assisted in the formation of nearly 20 start-up companies. Before commencing her career in university technology transfer, she founded her own plant biotechnology company, which was a spin-out from SIBIA, Inc., the Salk Institute's biotechnology company based in La Jolla, Calif. Dr. Fitzmaurice became head of SIBIA, Inc.'s Plant Sciences Program in 1985. She developed and managed the program for nearly 10 years, acquiring financial support from Hunt-Wesson Foods, Sumitomo Chemical, and Asahi Industries Company, Ltd., and creating technologies that were patented in U.S. and foreign jurisdictions. Dr. Fitzmaurice also worked at the National Institutes of Health (NIH) in Bethesda, Md., as a research expert introducing molecular biology techniques to immunology and cancer researchers and conducting research collaborations across the NIH campus. Her postdoctoral studies were conducted at the National Institute for Medical Research in Mill Hill (London, England), the University of Glasgow (Glasgow, Scotland), and UCLA. Dr. Fitzmaurice earned a bachelor's degree in biology from the University of Chicago and a Ph.D. degree in cellular and molecular biology from the University of Southern California.

Jeffrey S. Flier has been dean of the faculty of medicine at Harvard University since July 2007. Dr. Flier, an endocrinologist and an authority on the molecular causes of obesity and diabetes, is also the Caroline Shields Walker Professor of Medicine at Harvard Medical School. Previously (2002-2007), he had served as Harvard Medical School Faculty dean for academic programs and chief academic officer for Beth Israel Deaconess Medical Center (BIDMC), a Harvard teaching affiliate. Born in New York City, Dr. Flier received a bachelor's degree from City College of New York in 1968, and an M.D. degree from Mount Sinai School of Medicine in 1972, graduating with the Elster Award for Highest Academic Standing. Following residency training in internal medicine at Mount Sinai Hospital from 1972 to 1974, he moved to the National Institutes of Health as a clinical associate. In 1978, he joined the faculty of medicine at Harvard Medical School, serving as chief of the diabetes unit at Beth Israel Hospital until 1990, when he was named chief of the hospital's endocrine division.

Dr. Flier is one of the country's leading investigators in the areas of obesity and diabetes and has authored over 200 scholarly papers and reviews. His research has produced major insights into the molecular mechanism of insulin action, the molecular mechanisms of insulin resistance in human disease, and the molecular pathophysiology of obesity. An elected member of the Institute of Medicine and a fellow of the American Academy of Arts and Sciences, Dr. Flier's honors include the Eli Lilly Award of the American Diabetes Association, the Berson Lecture of the American Physiological Society, and an honorary doctorate from the University of Athens. He has been the recipient of a five-year \$500,000 Unrestricted Metabolic Research Grant by Bristol-Myers Squibb and the 2003 Edwin B. Astwood Lecture Award from the Endocrine Society. In 2005, he received the Banting Medal from the American Diabetes Association, its highest scientific honor. In 2008, Dr. Flier was awarded the Albert Renold Award from the American Diabetes Association for outstanding achievements in the training of diabetes research scientists and the facilitation of diabetes research.

Dr. Flier is married to Eleftheria Maratos-Flier, M.D., who is also on the faculty of Harvard Medical School and with whom he has collaborated on research in the area of neuroendocrine control of body weight. They have two daughters, Lydia and Sarah, and live in Newton, Mass.

Julie Gottlieb, M.A., is assistant dean at the Johns Hopkins University School of Medicine and directs the school's office of policy coordination. The office manages the review, development, and implementation of policies in areas such as conflict of interest and conflict of commitment, faculty interaction with industry, professional and research misconduct, and use of the Johns Hopkins' name. Ms. Gottlieb coordinated a major revision of the school's policy on conflict of interest, the development of a policy on institutional conflict of interest for the Johns Hopkins University and Health System, and the development of a policy on interaction with industry for Johns Hopkins Medicine. Her office administers the standing Committee on Outside Interests, its oversight subcommittees, the Standing Committee on Discipline, and policy development committees. Ms. Gottlieb has been an invited speaker at national and international meetings on conflict of interest and academic misconduct. She is a co-founder and president-elect of the AAMC Forum on Conflict of Interest in Academe, a network of professionals involved in conflict of interest policy development and administration at academic medical centers.

Ms. Gottlieb holds a master's degree from the Johns Hopkins University Nitze School of Advanced International Studies and a bachelor's degree from Brown University.

Harry Greenberg, M.D., received his bachelor's degree in history from Dartmouth College in 1966. He received his M.D. degree from Columbia College of Physicians and Surgeons in 1970. He did his internal medicine house staff and GI fellowship training at Bellevue Hospital and Stanford University, respectively. Dr Greenberg spent 10 years at the National Institutes of Health (NIH) in its laboratory of infectious disease as a tenured scientist before returning to Stanford in 1983. He is currently the Joseph D. Grant Professor of Medicine and Microbiology and Immunology and the senior associate dean for research at Stanford University School of Medicine. He is also a staff physician at the Palo Alto VA hospital. Dr Greenberg is a member of a variety of scholarly societies and editorial boards. He is currently president of the American Society of Virology and director of Stanford's NIH-funded CTSA.

Dr. Greenberg has been an active NIH-funded investigator for over 30 years, during which time his studies have focused primarily on viruses that infect the GI tract, liver, or respiratory tree. He has published more than 400 articles, chapters, and reviews during this time. His work has spanned the spectrum from basic studies of viral:host cell interaction to translation work on the immune response to important pathogens in both animal models and humans to clinical trials of vaccine safety and efficacy. He has trained many M.D. and Ph.D. postdoctoral students who are now in independent careers in science and academic medicine. He has also carried out a variety of other administrative roles at Stanford including being the chief of the GI division of the department of medicine, the acting chairperson of the department of medicine (twice) and the ACOS for research at the Palo Alto VA. During a two-year leave of absence from Stanford, Dr. Greenberg was chief scientific officer at a biotechnology company called Aviron (now MedImmune Vaccines), where he played a key role in bringing the live attenuated influenza vaccine to licensure.

Marianne Hockema currently serves as administrator for the Mayo Clinic Office of Conflict of Interest Review. This office is responsible for implementing institutional and individual conflict of interest policies as applied to research, purchasing, clinical practice, institutional investments, and leadership activities for Mayo Clinic in Rochester, Fla., and Arizona, and for 12 medical centers within the Mayo Health System. She also serves as staff to the Conflict of Interest Review Board and was a charter member of the task force that developed the institution's conflict of interest policies. In addition to her responsibilities in conflict of interest, she also served as administrator for the Medical-Industry Relations Committee for 15 years. Ms. Hockema joined Mayo Clinic in 1978 as director of public affairs for Saint Mary's Hospital.

Ms. Hockema holds a bachelor's degree in English and a master's degree in health services administration. She is co-founder of the Forum on Conflict of Interest in Academe, an affiliate of the Association of American Medical Colleges, and currently serves on its steering committee. She is also coauthor of "Principles and Process in the Development of the Mayo Clinic's Individual and Institutional Conflict of Interest Policy," published in *Mayo Clinic Proceedings*.

Ray Hutchinson, M.D., M.S., is associate dean for regulatory affairs at the University of Michigan Medical School and professor of pediatrics in its division of hematology/oncology in the department of pediatrics. He earned his degrees at Boston College, Dartmouth Medical School, and Harvard Medical School. In addition, he earned an M.S. degree in clinical research design and statistical analysis from the University of Michigan.

Dr. Hutchinson's responsibilities include assessment of the impact of regulatory requirements on medical school faculty in research, education, and clinical areas and promotion of compliance with accepted regulatory standards. He previously served as co-chair of the medical school's Institutional Review Board. He currently serves as chair of the University of Michigan Medical School Conflict of Interest board and co-chair of the University of Michigan Health System Compliance Committee. His academic interests lie in pediatric leukemia/lymphoma, in disclosure processes for faculty outside interests, in conflict of interest management, and in the regulations governing research on pregnant women and children.

Steven E. Hyman, M.D., is provost of Harvard University and professor of neurobiology at Harvard Medical School. From 1996 to 2001, he served as director of the National Institute of Mental Health (NIMH), the component of the National Institutes of Health charged with generating the knowledge needed to understand and treat mental illness. Before serving as director of NIMH, Dr. Hyman was professor of psychiatry at Harvard Medical School, director of psychiatry research at Massachusetts General Hospital, and the first faculty director of Harvard University's Mind, Brain, and Behavior Initiative. In the laboratory, he studied the regulation of gene expression by neurotransmitters, especially dopamine, and drugs that act on dopamine receptors.

Dr. Hyman is a member of the Institute of Medicine of the National Academy of Sciences, a fellow of the American Academy of Arts and Sciences, and a fellow of the American College of Neuropsychopharmacology. He is editor of the *Annual Review of Neuroscience* and first president of the Neuroethics Society. He received his bachelor's degree from Yale College in 1974, summa cum laude, and his master's degree from the University of Cambridge in 1976, which he attended as a Mellon fellow studying the history and philosophy of science. He earned his M.D. degree, cum laude, from Harvard Medical School in 1980.

Murray Kopelow, M.D., M.S. (Comm), F.R.C.P.C., is chief executive of the Accreditation Council for Continuing Medical Education (ACCME), where he leads the efforts to identify, develop, and promote standards for quality continuing medical education (CME) and to certify that providers of CME are meeting those standards. Dr. Kopelow has been responsible for the evolution of the accreditation system through the introduction of the 2000 criterion referenced new system, the 2004 update of the ACCME's Standards for Commercial Support: Standards to Ensure Independence, and the 2006 Updated Accreditation Criteria which position accredited "CME as a Bridge to Quality™". Prior to his current role, Dr. Kopelow practiced general, critical care, and emergency pediatric medicine at the Children's Hospital of Winnipeg, University of Manitoba, Canada, where he also served as associate dean for continuing medical education, director of programs for international medical graduates, and chair of the University Senate Committees on Instruction and Medical Qualifications.

Dr. Kopelow has had many opportunities to work on CME issues domestically and internationally, including serving as a member of the International "Rome" Group on Harmonization of CME/CPD credit and accreditation, being a participant in the work of the Federation of State Medical Boards' Special Committee on Maintenance of Licensure, and now as participant in the work of the American Board of Medical Specialties Maintenance of Certification Task Force. Having been active in studying evaluation tools for medical schools and credentialing organizations in both Canada and the United States, Dr. Kopelow is an author and coauthor of more than 30 articles on clinical practice and evaluation and assessment across the continuum of medical education. Dr. Kopelow received the Alliance for CME President's Award and the Frances Maitland Award as well as the Director's Award for Distinguished Service from the Office of Drug Control Policy of the Executive Office of the President of the United States.

A native of Canada, Dr. Kopelow holds a medical degree from the faculty of medicine, University of Manitoba, and a master's degree in communications systems from the department of communications studies at Northwestern University. He is a fellow of the Royal College of Physicians and Surgeons of Canada and a successful participant in that organization's maintenance of certification program.

David Korn, M.D., is vice provost for research at Harvard University and professor of pathology at Harvard Medical School. From 1997 to 2008, he served as senior vice president for biomedical and health sciences research, and in 2008, as chief scientific officer of the AAMC (Association of American Medical Colleges) in Washington, D.C.

Prior to his time at the AAMC, he served as the Carl and Elizabeth Naumann Professor and dean of the Stanford University School of Medicine from October 1984 to April 1995, and as vice president of Stanford University from January 1986 to April 1995. Before that he had served as professor and chair of the department of pathology at Stanford, and chief of the pathology service at the Stanford University Hospital, since June 1968.

Dr. Korn received his bachelor's degree from Harvard College and medical degree from Harvard Medical School. He completed his residency training at Massachusetts General Hospital. He has been chair of the Stanford University Committee on Research; president of the American Association of Pathologists (now the American Society for Investigative Pathology), from which he received the Gold-Headed Cane Award for lifetime achievement in 2004; president of the Association of Pathology Chairmen; a member of the board of directors and the executive committee of the Federation of American Societies for Experimental Biology; and a member of the board of directors of the Association of Academic Health Centers. Dr. Korn was a founder and chair of the board of directors of the California Transplant Donor Network, one of the nation's largest organ procurement organizations.

More recently, he was a founder of the Association for the Accreditation of Human Research Protection Programs, a nonprofit corporation created to enhance and standardize the protection of human participants in medical research. He is a member of the Institute of Medicine of the National Academy of Sciences, and has served on numerous National Academies committees. In the past decade, his writings and lectures have focused on issues of academic values and health and science policy.

David E. Longnecker, M.D., F.R.C.A., is a director in the division of health care affairs of the AAMC (Association of American Medical Colleges), and the Robert D. Dripps Professor Emeritus of anesthesiology and critical care at the University of Pennsylvania. At the AAMC, he coordinates a national organization for chief medical officers and he co-leads an AAMC initiative to enhance the culture of quality and safety in AAMC member organizations.

Dr. Longnecker came to the AAMC from the University of Pennsylvania, where he served as chair of anesthesiology, vice dean for professional services, and senior vice president-corporate chief medical officer of the University of Pennsylvania Health System. In the latter role, he was responsible for quality, safety, clinical IT, and clinical quality improvement initiatives across the hospital system. He has written numerous scientific articles and chapters and has edited seven medical textbooks, including the 2,200-page *Anesthesiology* (2007) and the online anesthesia education Web site, *AccessAnesthesiology* (live Feb 2009).

Dr. Longnecker is a fellow (by election) of the Royal College of Anaesthetists and member of the Institute of Medicine (IOM) of the National Academy of Sciences. At the IOM, he chairs the Committee on Aerospace Medicine and Medicine for Extreme Environments, which advises NASA on crew health and medical care associated with space flight, including plans for return to the moon and eventual human exploration of Mars. He chairs the Biomedical Committee of the NASA Advisory Council, which advises the NASA administrator on strategic initiatives. His personal interests include protection of the coastal environment, and he is a member of the advisory board of the Smithsonian Environmental Research Center.

Ross E. McKinney Jr., M.D., is a native of Kansas who graduated from Dartmouth College and obtained his M.D. degree from the University of Rochester School of Medicine and Dentistry in New York. He arrived in Durham, N.C., for his internship in pediatrics and never left. While at Duke, Dr. McKinney has served as an intern, resident, fellow (in pediatric infectious diseases), and faculty member (currently professor of pediatrics, molecular genetics, and microbiology). He has been the division chief in pediatric infectious diseases (1994-2003), vice dean for research in the school of medicine (2002-2007), and is currently director of the Trent Center for Bioethics, Humanities, and History of Medicine. He is also chair of the Duke University School of Medicine Conflict of Interest Committee. His research interests have focused on the treatment of children with HIV infection. He has served as the chair of the Infectious Diseases Sub-board of the American Board of Pediatrics, on the executive committees of the Pediatric Infectious Diseases Society, North Carolina Pediatric Society, and the National Institutes of Health-funded Pediatric AIDS Clinical Trials Group and Pediatric Pharmacology Research Unit Network, and as a member of the steering committee for the AAMC Group on Research and Development (GRAND) (2006-2008). He is current chair of the steering committee for AAMC Forum on Conflict of Interest in Academe (2008-2010).

Dr. Sally Rockey is acting deputy director for extramural research and acting director of the Office of Extramural Research (OER), leading the extramural research activities of the National Institutes of Health (NIH). OER serves as the focal point for policies and guidelines for extramural research administration within NIH.

Dr. Rockey received her Ph.D. degree in entomology (1985) from Ohio State University, and has spent most of her career in the area of extramural research and information technology. She is active on a number of federal intergovernmental committees related to science, research, grants management, and electronic government, and collaborates closely with academic and scientific communities.

In 1986, Dr. Rockey joined the U.S. Department of Agriculture's Extramural Research arm where she quickly rose to the post of deputy administrator for the Competitive Research Grants and Award Management Unit, overseeing competitive research, education, and extension portfolios. By 2002, she had become chief information officer (CIO), applying her breadth of government knowledge to IT, aligning state-of-the-art information technologies with the department's goals and objectives. In 2005, Dr. Rockey was appointed to the position of deputy director of OER within the Office of the Director at the NIH where she applied her experience in research and grants administration to public health. She also served as acting director of the Office of Research Information Systems in OER where she again used her CIO experience to oversee the eRA (electronic research administration) and OER reporting activities. In 2008, Dr. Rockey became the acting NIH deputy director for extramural research.

Dr. Rockey is an accomplished public speaker, and has given countless presentations on extramural research priorities and policies, grantsmanship, the competitive peer-review process, scientific integrity, and IT. Among her many professional accomplishments, such as receiving the Presidential Rank Award in 2004, Dr. Rockey actively encouraged the science education of young children, giving presentations on insects to local elementary schools where she was known as the "Bug Doctor."

Mike Saxton, M.Ed., F.A.C.M.E., C.C.M.E.P., currently serves as a team member of Pfizer's Medical Education Group within the CMO division of Medical Communications, Education, and Grants. Long an advocate for change within the pharmaceutical industry in terms of how it supports continuing professional development of health care providers, he combines 28 years of pharmaceutical industry, CME provider, and consulting experience in the area of CME best practices relative to commercial support issues. The winner of numerous service awards within the CME profession, his past volunteer activities have included the Alliance for Continuing Medical Education (ACME) board of directors, CME Advancement Task Force, AMA National Task Force on CME Provider & Industry Collaboration, chair of the 2007 ACME Annual Conference, editorial board of JCEHP (*Journal of Continuing Education in the Health Professions*), and co-chair of the Pharmaceutical Alliance for CME (PACME).

Mr. Saxton's career began in Virginia, with subsequent moves to Maryland, Michigan, and now New Jersey where he works at Pfizer's global headquarters in Manhattan. The father of four, he and his wife reside in New Jersey. When not spending time with his family, he is an avid Appalachian Trail backpacker, and also enjoys kayaking and genealogy.

Allen M. Spiegel, M.D., an internationally recognized researcher and endocrinologist, became dean of the Albert Einstein College of Medicine of Yeshiva University in June 2006.

Prior to joining Einstein, Dr. Spiegel was director of the National Institute of Diabetes and Digestive Diseases and Kidney Diseases (NIDDK) at the National Institutes of Health (NIH), the culmination of a distinguished 33-year career at the NIH.

A member of the Institute of Medicine of the National Academy of Sciences, Dr. Spiegel earned his bachelor's degree, summa cum laude, and Phi Beta Kappa from Columbia University in 1967. He received his M.D. degree, cum laude, from Harvard Medical School in 1971 and completed his clinical training at Massachusetts General Hospital.

Dr. Spiegel began his career at the NIH in 1973 as a clinical associate in its endocrinology training program. He then served as a senior investigator in its Metabolic Disease Branch from 1977 to 1984. In 1985, he was appointed chief of molecular pathophysiology, and then chief of the Metabolic Diseases Branch. In 1990, he was appointed director of the NIDDK's Division of Intramural Research. He served in these various capacities until his appointment as director of the NIDDK in 1999. In this role, Dr. Spiegel was responsible for a staff of 625 full-time employees and a \$1.7 billion budget.

Dr. Spiegel is a widely renowned physician-scientist and endocrinologist with extensive experience in translational research programs. His research has centered on G-protein-regulated signaling dysfunction in human disease, and his work on signal transduction helped to clarify the genetic basis of several endocrine diseases. He has published extensively, with more than 250 peer-reviewed papers and 100 reviews and book chapters to his name, as well as two books on G proteins.

Samuel L. Stanley Jr., M.D., has been a member of the Washington University community since 1983, when he began a fellowship in infectious diseases at the school of medicine. He rose through the ranks in the school's department of medicine to become a professor of medicine in 1999, and in 2004 was appointed a professor in the department of molecular microbiology as well in recognition of the collaborative and interdepartmental nature of his research.

A Seattle native, Dr. Stanley has a bachelor's degree in biological sciences (Phi Beta Kappa) from the University of Chicago and earned his medical degree from Harvard Medical School in 1980. He completed his resident-physician training at Massachusetts General Hospital, a teaching hospital of Harvard Medical School.

As vice chancellor for research, Dr. Stanley is the chief officer responsible for the university's research missions, overseeing an enterprise that generates more than \$550 million for sponsored research from a wide array of funding sources. He is the university's institutional official responsible for all compliance programs that oversees the university community's adherence to guidelines governing laboratory animal care and use and research involving human volunteers.

His areas of oversight also include development of research policies, management of grants and contracts, the continuing education of faculty and staff regarding research regulations, issues related to conflict-of-interest and research integrity, and intellectual property and technology transfer. He has focused on developing new IT solutions and new organizational structures to reduce the burden of research compliance on faculty, while strengthening education in areas like conflict of interest, ethics, and human subjects research. Dr. Stanley reorganized the office of technology transfer at Washington University, and implemented several new programs to reach out to faculty and help them along the pathway of bringing innovative discoveries from concept to product.

Dr. Stanley, who has had long-running and substantial research support from the federal government's National Institutes of Health (NIH), is an expert in the biological mechanisms cells employ when responding to infectious agents such as parasites, bacteria, and viruses, a process commonly called the inflammatory response. Better defense against infection is a key focus of his research. Recently, he has begun to focus on specific genetic factors that might make serious side effects more common in some persons receiving vaccines.

Among the several research grants that Dr. Stanley leads is the nearly \$37 million grant from the NIH to create the Midwest Regional Center of Excellence in Biodefense and Emerging Infectious Diseases Research, based at Washington University. The multi-institutional center is developing methods to rapidly identify new pathogens and find means to control or neutralize them.

Dr. Stanley has been appointed as president of Stony Brook University in Stony Brook, N.Y., effective July 1, 2009.

Patrick White is vice president for federal relations at the Association of American Universities (AAU). Mr. White is responsible for developing and implementing the federal relations strategy of the association staff, who serve the presidents and chancellors of AAU's 62 public and private research universities. He is specifically responsible for biomedical research issues, including budget and appropriations for the National Institutes of Health (NIH), individual and institutional conflicts of interest, human research subjects protections, human embryonic stem cell research, and the use of animals in research. He shares responsibility for other research policy issues, including indirect costs, scientific merit review, technology transfer, and institutional regulations and compliance burdens.

Prior to joining AAU in December 2003, Mr. White served as director of legislative relations for the Federation of American Societies for Experimental Biology (2000-2003), director of public affairs for the American Association of Immunologists (1993-2000), external affairs officer for Presidential Science Advisor D. Allan Bromley (1992-1993), and chief of staff for Congressman Robert W. Davis (1989-1992).

Mr. White has been a member of the executive committee of the Ad Hoc Group for Medical Research since 1994, a board member of the Coalition for the Advancement of Medical Research since 2004, and served on the Institutional Animal Care and Use Committee at George Mason University (1998-2000). In November 2006, he began service on Georgetown University Medical Center's Oncology Institutional Review Board.

Mr. White earned an A.B. degree in English and philosophy from Georgetown University (1982), a master's degree in international transactions from George Mason University (1996), and has taken courses in immunology and recombinant DNA at the Foundation for Advanced Education in the Sciences at NIH.

Regina H. White, M.B.A., became Brown University's associate vice president for research administration in September 2003. She oversees all aspects of research administration and research compliance, and she serves as an advocate for researchers in the funding information, application, and post-award oversight processes. She is responsible for, and works closely with, the Office of Sponsored Projects, the Research Protections Office, and the Research Compliance Network, and chairs the university's Conflict of Interest Review Board.

Ms. White comes to Brown from the National Institutes of Health (NIH), where she directed its Office of Policy for Extramural Research Administration. At NIH, she was responsible for overseeing a complex system of research-related activities, including grants policy, grants oversight and compliance, and extramural information systems. Before going to NIH, Ms. White was director of the Office of Sponsored Programs at the University of Vermont, prior to which she was a senior assistant director at Harvard University's Office for Sponsored Research. Ms. White is a native of Rhode Island, and holds an M.B.A. degree from Boston University.

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