

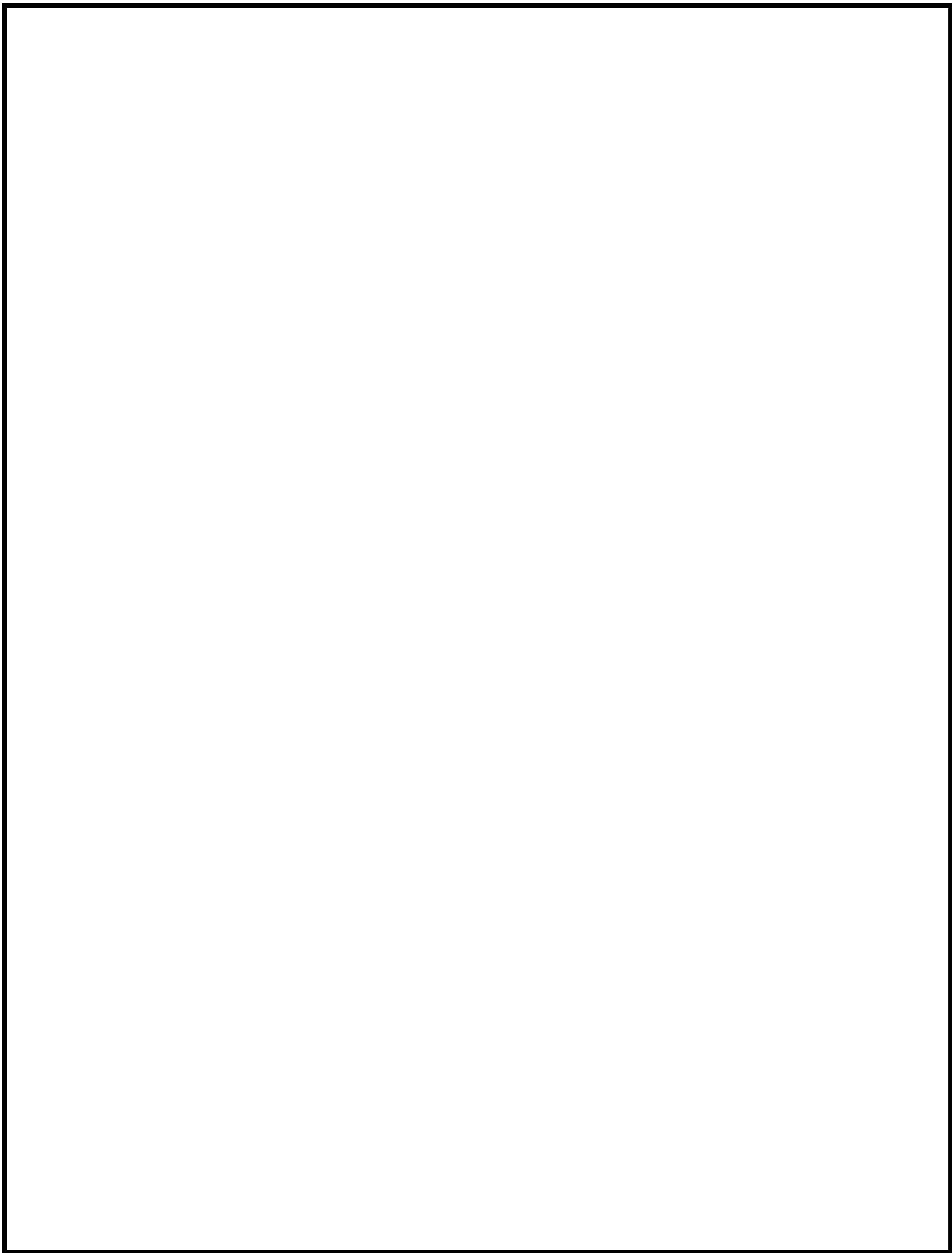
# ***Prescription for Conflict***

Friday, June 25, 2010

Georgetown University  
Washington, DC

***Should Industry Fund Continuing  
Medical Education?***





Continuing medical education (CME) is required for most physicians, nurses, and physician assistants, and plays a key role in influencing patient care decisions and ultimately public health. In 2008, 44% of the \$2.4 billion spent on CME came from pharmaceutical manufacturers. Sixty-nine percent of the income from events sponsored by medical education companies and 54% of CME income to academic medical centers comes from industry. Proponents argue that industry-funded CME can be fair and balanced and keeps costs down. Opponents argue that commercially-funded CME biases physicians towards targeted drugs.

We have brought together a diverse group of speakers representing academia, government, industry, and the nonprofit sector to address the question: Does industry funding affect the educational content of CME?

This conference was made possible by a grant from the Georgetown University Reflective Engagement Initiative. The conference is an interdisciplinary collaboration among the Georgetown University Medical Center, Law Center, and Kennedy Institute of Ethics. The lead researcher, Adriane Fugh-Berman, MD, is an Associate Professor in the Department of Physiology and Biophysics, and director of the Georgetown University project PharmedOut. Edmund Pellegrino, MD, is Professor Emeritus of Medicine and Medical Ethics and Senior Research Scholar, Kennedy Institute of Ethics. Michael Frisch, JD is an Adjunct Professor of Law and the Ethics Counsel to the Law Center; and Anthony Scialli, MD is Adjunct Professor in the Department of Obstetrics and Gynecology.

This conference would not be possible without PharmedOut's fabulous (and only) staffperson, Alicia M. Bell, who has been an amazing conference coordinator, and our wonderful volunteers. Judy Davis coordinated the reception. Our heartfelt thanks to our other volunteers, who include

Dot Coffey  
Ayden Cooper  
Judy Davis  
Brooke Grandle  
Maggie Infeld  
Beth Johnson  
Sean Kenmore

Skip Krafft  
Danielle LaSalandra  
Charlea Massion  
Antonie Meixel  
Sue Mulrone  
Adam Myers  
Amy Richards

Emmett Soper  
Jen Stuart  
Allison Tomson  
Christopher Wee  
Elena Yanchar  
Jessie Zak  
...And others

Special thanks to Daniel Carlat

Special thanks to Michael Snead, Leavey Center Chef at the Faculty Club

Thanks also to Tressa Kirby, Karen Mallet, Jayme Hommer, Janisa LaSalle, Colleen Whalen, Sharon Radzaminski, Megan Angevine, and Satindar Kaur

Thank you to Dr. Stephen Ray Mitchell, Dean for Medical Education, GUMC for supporting medical student scholarships. Contributions for student scholarships were also made by Gordy Schiff MD, Fred Sierles MD, Wells Wilkinson JD, and Lisa Robin.

*For food contributions, we thank*

*GTU Reflective Engagement Grant*

*Whole Foods Market in Georgetown*

*Trader Joe's at Foggy Bottom*

*Route 11 Potato Chips*

*We thank Nick Perez, Multiflor Inc. for the floral arrangement*

The three artworks (*R[e]x*, *Pharmaceutically-enhanced Chest*, and *Pen Tempest*) were assembled by Barbara Leckie & Clare Wilson, of the WSP Daughters' Collective.

Catering provided by the Corp, the world's largest completely student owned and operated business and 501(c)(3) non-profit organization, and the French Embassy.

**Prescription for Conflict:  
Should Industry Fund Continuing Medical Education?  
Friday, June 25, 2010**

**Georgetown University Intercultural Center Auditorium Washington, DC**

**Agenda**

**7:30-8:00am**

***Registration, Continental breakfast***

**8:00-8:15am *Opening Remarks***

Stephen Ray Mitchell, MD, Dean for Medical Education  
Georgetown University Medical Center

Thomas Insel, MD, Director, National Institute of Mental Health, National Institutes of Health

Anthony Scialli, MD, Clinical Professor of Obstetrics and Gynecology, George Washington University School of Medicine

**8:15-8:45am**

***Drug Companies and Medical Knowledge***

Joel Lexchin, MD, Professor, York University and University of Toronto

**8:45-10:00am**

***What's Known About Industry Influence on Continuing Education of Prescribers?***

Elissa Ladd, PhD, RN, Assistant Clinical Professor, MGH Institute of Health Professions

Daniel Carlat, MD, Associate Clinical Professor of Psychiatry, Tufts University School of Medicine, Editor, Carlat Psychiatry Report

Adriane Fugh-Berman, MD, Associate Professor, Georgetown University Medical Center

Jeremy Greene, MD, PhD, Assistant Professor, Harvard University

**10:00-10:30am**

***Break***

**10:30-11:15am *Professionalism***

Edmund Pellegrino, MD, Professor Emeritus of Medicine and Medical Ethics, Kennedy Institute of Ethics, Georgetown University

Michael Frisch, JD, Ethics Counsel Georgetown University Law Center

**11:15am-12:00pm *Federal Views***

Joshua Sharfstein, MD, Principal Deputy Commissioner, U.S. Food and Drug Administration

Paul Thacker, Senior Investigator, Office of Senator Chuck Grassley

Julie Taitzman, JD, MD, U.S. Department of Health and Human Services Office of Inspector General

**12:00-1:15pm**

***Lunch (Leavey Conference Center Program Room)***

**1:15-1:45pm**

***Bioethicists and Pharma***

Carl Elliott, MD, PhD, Professor, Center for Bioethics, University of Minnesota School of Medicine

**1:45-2:30pm**

***Views from Former Insiders***

Mark Helm, MD, MBA, Helm Benefit Design, President

Douglas Melnick, MD, MPH, Physician, Los Angeles, CA

Glenn Demott, MS, Columbus, OH

**2:30-2:45pm**  
**Break**

**2:45-4:00pm Pros and Cons of Industry-Funded Education**

Maureen Doyle-Scharff, MBA, FACME, Senior Director, Team Lead, Medical Education Group, External Medical Communications, Pfizer, Inc

Norman Kahn, MD, Executive Vice-President and CEO, Council of Medical Specialty Societies

David Davis, MD, Senior Director, Continuing Education and Performance Improvement, Association of American Medical Colleges

Mike Saxton, MEd, Consultant

Douglas Melnick, MD, MPH, Physician, Los Angeles, CA

Moderator: Alicia Mundy, Wall Street Journal

**4:00-4:45pm**  
**Is Industry-free CME a Sustainable Model?**

Robert Wittes, MD, Physician-in-Chief, Memorial Sloan-Kettering Cancer Center

Steve Willis, MD, Professor, East Carolina University, Executive Director, Eastern Area Health Education Center

Hanadi Shamkhani, MD, RPh, Kaiser-Permanente

**4:45-5:30pm**  
**Next Steps-Discussion**

**5:30-7:00pm**  
**Reception (Leavey Conference Center Program Room)**

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**About PharmedOut**

PharmedOut, a project based at Georgetown University Medical Center, educates prescribers about how covert marketing techniques affect prescribing behavior. Our goal is to foster evidence-based, cost-effective prescribing and to decrease the adverse public health effects of inappropriate pharmaceutical promotion.

Our unique approach draws on marketing materials, studies from the business, social sciences and medical literature, and original interviews with industry insiders to create novel articles, videos, and educational materials. Launched through a 2006 grant from the Attorney General Consumer and Prescriber Grant Program, PharmedOut is currently funded solely through individual donations.

**The Georgetown Reflective Engagement Initiative**

*"As the leading research institution in the nation's capital, Georgetown University attracts some of the most talented faculty and students in the world. They join an intellectual community that offers unlimited opportunities to engage with the pressing issues of the day. This dynamic setting gives scholars an immediate focus for their research and teaching, while also providing a place to practice the values that lie at the core of Georgetown's educational mission.*

*That we do and should engage with the Washington world is almost a given. But how we should engage raises difficult questions. When scholars at great universities examine and expose root causes, structures of thought and analysis, and power relations, they maintain a critical stance toward politics, commerce, arts, and entertainment. And yet, many constituencies are calling on research universities to do more to use knowledge to serve the world. Thus universities face the challenge of remaining above the fray, while also encouraging scholars to seize more opportunities to shape ideas and influence public debate.*

*In August 2004, President John DeGioia charged Executive Vice President and Dean of the Law Center Alex Aleinikoff to consider how Georgetown should engage more deeply in the public arena. Dean Aleinikoff formed a steering group of faculty to develop an initiative that responds to the charge. In conversations with members of the Georgetown*

*community and Washington DC constituencies, the group determined that Georgetown could be a forum for authentic dialogue, provide helpful methodologies, and bring multiple perspectives to bear on issues that could be of benefit of to policymakers and practitioners in the nation and the District.”*

### **Accreditation Statements**

This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education through joint sponsorship of American Physician Institute for Advanced Professional Studies LLC and The Clearview CME Institute. The Clearview CME Institute is accredited by the ACCME to provide continuing medical education for physicians. The Clearview CME Institute designates this educational activity for a maximum of 5 AMA PRA Category 1 Credits™. Participants should claim credit commensurate only with the extent of their participation of the activity.

This activity has been approved for 6.0 Continuing Education Units by Georgetown University, Department of Nursing, an approved provider of continuing nursing education by the Maryland Nurses Association, an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation.

### **Speaker Bios**

*Daniel Carlat, MD, Associate Clinical Professor of Psychiatry, Tufts University School of Medicine, Editor, Carlat Psychiatry Report*

Dr. Carlat is Associate Clinical Professor of Psychiatry at Tufts University School of Medicine, and is the Editor-in-Chief of The Carlat Psychiatry Report, a monthly newsletter on psychopharmacology widely read by psychiatrists and nurses in the United States. The Carlat Psychiatry Blog is consistently ranked as one of the 10 most influential health blogs by Wikio, and has received an award for outstanding mental health journalism by the Psych Central Website. Dr. Carlat's textbook, *The Psychiatric Interview*, currently in its second edition, has been translated into four languages, and is the bestselling book in the Practical Guide series. It was selected as one of 17 top recommended psychiatric books on the Brandon/Hill Selected List of print media for small medical libraries. His new book, *Unhinged: The Trouble with Psychiatry*, was published in May of 2010.

*David Davis, MD, Senior Director, Continuing Education and Performance Improvement, Association of American Medical Colleges*

Currently the AAMC's lead for continuing healthcare education and improvement, Dr. Davis was a family physician in Ontario, Canada for nearly forty years. For much of that time, he was active in 'CME' as: chairman of an all-staff inter-professional CE 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 (Implementation Science) Program in the Faculty of Medicine, University of Toronto; and chairman of Ontario's Guidelines Advisory Committee.

Dr. Davis has also developed an innovative comprehensive competency assessment program for the provincial licensing body, and helped create a center for faculty development and a Mini-Med School at the University of Toronto. Emphasizing evaluation of educational activities using a rigorous outcomes-testing approach, he has acted as PI, Co-PI or investigator on grants totaling several million dollars. This emphasis has seen the publication of 125 peer-reviewed papers, in addition to dozens of abstracts, book chapters, 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. Dr. Davis has also 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.

*Glenn Demott, MS, Columbus, OH*

Mr. Demott is one of the whistleblowers whose efforts led to the government's \$2.3 billion settlement with Pfizer in the fall of 2009. Mr. Demott initiated his lawsuit under the qui tam provisions of the Federal False Claims Act. He was employed in pharmaceutical sales for 18 years and has earned numerous national sales awards. Mr. Demott has a master's degree from Oregon State University in fish and wildlife biology with a minor in statistics.

*Maureen Doyle-Scharff, MBA, FACME, Senior Director, Team Lead, Medical Education Group, External Medical Communications, Pfizer Inc.*

Ms. Doyle-Scharff has worked in the field of medical education for nearly 20 years. She currently serves on the Board of Directors for the Alliance for Continuing Medical Education (ACME) as Treasurer, and the Global Alliance for Medical Education (GAME), is a member of the American Medical Association's National Task Force on Provider/Industry CME Collaboration, and is founder and immediate-past president of the Ohio Affiliate of the Healthcare Businesswomen's Association. Ms. Doyle-Scharff received her undergraduate degree from the University of Michigan, her MBA from St. Joseph University and is currently a doctoral student in Higher Education at Ohio University.

*Carl Elliott, MD, PhD, Professor, Center for Bioethics, University of Minnesota School of Medicine*

Carl Elliott teaches bioethics and philosophy at the University of Minnesota. He is the author or editor of six books, including *Better than Well: American Medicine Meets the American Dream*. His articles have appeared in publications such as *The New Yorker*, *The Atlantic Monthly*, and *The London Review of Books*, as well as *The New England Journal of Medicine*. In 2003-04, he was a Visiting Associate Professor at the Institute for Advanced Study in Princeton, New Jersey, where he led a faculty seminar on bioethics. His book, *White Coat, Black Hat*, will be published by Beacon Press in the fall of 2010.

*Michael Frisch, JD, Ethics Counsel, Georgetown University Law Center*

Mr. Frisch is the Ethics Counsel of Georgetown University Law Center and teaches professionalism and legal ethics to law students. He has served as Senior Assistant Bar Counsel to the District of Columbia Court of Appeals, was in private practice from 1978-84 and was Assistant Federal Public Defender for Maryland from 1975-78. Mr. Frisch was also a research assistant for the Senate Watergate Committee in 1973 and 1974. He currently serves as a member of the Committee on Admissions and Grievances of the United States Court of Appeals for the District of Columbia Circuit.

*Adriane Fugh-Berman, MD, Associate Professor, Georgetown University Medical Center*

Dr. Fugh-Berman, MD is an Associate Professor in the Department of Physiology and Biophysics and in the Department of Family Medicine at Georgetown University Medical Center. Her areas of research include pharmaceutical marketing practices and the culture of medicine. Dr. Fugh-Berman directs PharmedOut (<http://pharmedout.org>), an independent, Georgetown University-based project supported by individual donations. PharmedOut does research on and educates physicians about inappropriate pharmaceutical marketing practices. Additionally, Dr. Fugh-Berman teaches within the first basic sciences complementary and alternative medicine (CAM) master's program in the United States. Dr. Fugh-Berman consults on the risks and benefits of herbs and dietary supplements for various federal and state agencies. Previously, she was a medical officer in the Contraception and Reproductive Health Branch of the National Institute for Child Health and Human Development at NIH. She has also worked with the Reproductive Toxicology Center and edited an award-winning CME

newsletter on women's health. Prior to that she worked at the NIH Office of Alternative Medicine (now the National Center on Complementary and Alternative Medicine).

Dr. Fugh-Berman graduated from Georgetown University School of Medicine and completed a family medicine internship in the Residency Program in Social Medicine at Montefiore Hospital in the Bronx. She is the author of the *5-Minute Herb and Dietary Supplement Consult* (Lippincott, Williams and Williams, 2003), a clinician's handbook, and *Alternative Medicine: What Works* (Williams and Wilkins, 1997). She coauthored *The Truth about Hormone Therapy* (Prima, 2002) and co-edited *The Teratology Primer* (Teratology Society, 2005). Dr. Fugh-Berman has published dozens of peer-reviewed articles and consumer publications in three distinct fields: pharmaceutical marketing, women's health, and the risks and benefits of herbal medicines. An internationally known speaker, Dr. Fugh-Berman has appeared on *20/20*, the *Today Show*, and *Nightline*, and every major news network.

*Jeremy Greene, MD, PhD, Assistant Professor, Harvard Medical School*

As an internationally recognized historian of the American pharmaceutical industry, a member of highly regarded faculties of history of science and pharmacoepidemiology, and a practicing internist at a large academic medical center, Dr. Greene has completed a number of research projects relevant to the question of industry influence in continuing medical education. Dr. Greene is trained in archival, literature-based, and oral historiography, having received an MA in Medical Anthropology and a PhD in the History of Science from Harvard University, with particular expertise in the history of American pharmaceutical development, marketing, regulation, and utilization in the late 20th century. He has an extensive track record of publications and presentations on the history and ethnography of medication use and has written broadly on the evolution of therapeutic rationalism for clinical, policy, and scholarly audiences. His first book, *Prescribing by Numbers: Drugs and the Definition of Disease* was published by the Johns Hopkins University Press in 2007 and received the Rachel Carson Award from the Society for the Social Study of Science for a book-length work of extraordinary social and political relevance.

*Mark E. Helm, MD, MBA, Helm Benefit Design, Inc*

Prior to pursuing a medical degree, Dr Helm earned a Master of Business Administration degree from the Pennsylvania State University. He began his pharmaceutical career at IMS America, the world's largest provider of marketing research information for the pharmaceutical industry. After several years, Mark moved into a market research position with Miles Pharmaceuticals the American arm of Bayer Pharmaceutical Division. At Bayer, Mark worked on cardiovascular and emerging products as well as managed care market research. In 1996, Mark moved to Georgia and worked for UCB pharmaceuticals on their full product line. Dr. Helm's work in industry provided a strong background in understanding the influence of the pharmaceutical industry marketing on various aspects of prescriber decision-making.

Dr. Helm completed medical school in 2001 and his pediatric residency in 2004. After residency Dr. Helm served as Medical Director for the Arkansas Medicaid Evidence-based Prescription Drug Program. In this role, he also provided consultation services to the Arkansas State Employee Benefit Division regarding their pharmacy benefits. Working primarily with Medicaid administrative claims data, Dr. Helm has studied the impact of various methods to affect medication use patterns. Dr. Helm has developed and delivered a number of programs for continuing education for family physicians, pediatricians, psychiatrists, nursing and respiratory therapists. Recently Dr. Helm completed a large project funded through Neurontin settlement monies to influence prescriber behavior regarding treatment of anxiety and depression in children and adolescents. In addition to

his pharmacy benefit consulting work, Dr. Helm is also in clinical practice seeing pediatric outpatients in Little Rock, Arkansas.

*Thomas Insel, MD, Director, National Institute of Mental Health, National Institutes of Health*  
Dr. Insel is the Director of the National Institute of Mental Health (NIMH). In this role, since 2002, he has led the nation's investment for research on the causes and treatments of mental disorders. His tenure at NIMH has been marked by a commitment to the problems of individuals and families with serious mental illness, with a focus on specific public health outcomes. In addition to his leadership of NIMH, Dr. Insel serves as the chair of the Interagency Autism Coordinating Committee for the Secretary of the Department of Health and Human Services. While trained as a physician (graduating from the combined BA-MD program at Boston University in 1974) and a psychiatrist (completing residency at the Langley Porter Neuropsychiatric Institute at the University of California, San Francisco in 1979), Dr. Insel spent most of his scientific career as a basic neuroscientist focused on the molecular basis of complex social behaviors, such as social attachment. Prior to his current position at NIMH, Dr. Insel served as Director of the Yerkes Regional Primate Center (1994-1999) at Emory University and founding Director of the Center for Behavioral Neuroscience (1999-2002) in Atlanta, Georgia. He has published over 250 scientific articles and four books, including the *Neurobiology of Parental Care* (with Michael Numan) in 2003. He is a member of the Institute of Medicine and a recipient of many awards including the 2010 Ipsen Prize.

*Norman Kahn, MD, Executive Vice-President and CEO, Council of Medical Specialty Societies*  
Dr. Kahn serves as Executive Vice-president and Chief Executive Officer of the Council of Medical Specialty Societies (CMSS). CMSS represents 34 medical specialty societies with an aggregate membership of over 650,000 physicians. Dr. Kahn has served on numerous boards and committees, including the Accreditation Council for Continuing Medical Education, where he chaired the Task Force that revised the Standards for Commercial Support of CME. He has served on a subcommittee on Clinical Decision Support of the American Health Information Community (AHIC), as well as a Technical Expert Panel on Clinical Decision Support of the Office of the National Coordinator (ONC) for Health Information Technology.

Dr. Kahn serves on the National Steering Committee, and Chairs the National Advisory Committee of the Improving Performance in Practice (IPIP) project, funded by the Robert Wood Johnson Foundation to the American Board of Medical Specialties (ABMS). He also represents CMSS to several quality and performance measurement and improvement agencies, including the Physicians Consortium for Performance Improvement (PCPI) and the National Quality Forum (NQF).

*Elissa Ladd, PhD, RN, Assistant Clinical Professor, MGH Institute of Health Professions*  
Dr. Ladd has been a nurse practitioner for 25 years and has taught in nurse practitioner graduate level programs for 15 years. Dr. Ladd has practiced in a wide variety of primary care settings including community health centers, homeless shelters, health maintenance organizations and the Indian Health Service. She has taught in graduate programs in nursing at the University of Massachusetts and most recently at the MGH Institute of Health Professions. Dr. Ladd received her undergraduate nursing degree from the University of Pennsylvania, Master of Science degree from Rush University and PhD from the University of Massachusetts. Her research interests are in pharmaceutical policy and prescribing behaviors. She has lectured extensively and been involved in the planning of continuing education programs that pertain to evidence-based prescribing for advanced practice nurses. Dr. Ladd was the only nurse to receive one of 28 grants awarded across the country by the US Attorneys General Consumer and Prescriber Education Grant program and is

currently involved in developing evidence-based online materials on pharmaceuticals for consumers and prescribers.

*Joel Lexchin, MD, Professor, York University and University of Toronto*

Dr. Lexchin has authored over ninety peer reviewed publications dealing with various aspects of the pharmaceutical industry, such as physician prescribing behavior, pharmaceutical patent issues, the drug approval process and prescription drug promotion, both in Canada and internationally. He has given numerous talks about pharmaceutical policy, especially the interactions between industry and the medical profession. Dr. Lexchin received his MD from the University of Toronto in 1977 and for the past 23 years has been an emergency physician at The University Health Network. He is currently a Professor in the School of Health Policy and Management at York University and an Associate Professor in the Department of Family and Community Medicine at the University of Toronto. He has been a consultant on pharmaceutical issues for the province of Ontario, various arms of the Canadian federal government, the World Health Organization, the government of New Zealand and the Australian National Prescribing Service.

*Douglas Melnick, MD, MPH, Preventive Medicine Physician, Los Angeles, California*

Dr. Melnick currently manages public health projects and is a clinical specialist in a public health clinic. He also has practical experience in combining clinical medicine with public health and medical ethics. He has extensive knowledge in pharmaceutical marketing, health promotion, and evidence-based medicine. Dr. Melnick is a graduate of the David Geffen School of Medicine at UCLA and, prior to working in public health, he spent over five years working in medical affairs in the pharmaceutical industry supporting pharmaceutical marketing, medical review of promotional materials, competitive intelligence, and the publication of industry abstracts, posters, and papers.

*Stephen Ray Mitchell, MD, Dean for Medical Education, Georgetown University Medical Center*

A Dreyfuss National Merit Scholar at the University of North Carolina, Dr. Mitchell completed training and certification in internal medicine and pediatrics at the North Carolina Memorial Hospital in Chapel Hill. He completed rheumatology subspecialty training at Georgetown University. In 1988, he accepted a faculty position to provide rheumatology teaching and service in adult and pediatric rheumatology at Georgetown University Hospital, where he opened the Childhood Arthritis Center. Dr. Mitchell served as Residency Program Director in Internal Medicine from 1992 to 1999 and initiated an innovative Medicine Pediatric Residency at Georgetown in partnership with Kaiser Permanente in 1996 under the sponsorship of Partnerships for Quality Education and the Pew Charitable Trusts. He has served on the Council and Secretary Treasurer of the Association of Program Directors in Internal Medicine (APDIM) from 1996 to 2002. Dr. Mitchell served as Associate Dean for Clinical Curriculum at Georgetown University School of Medicine from 1998 to 2000 and Senior Associate Dean for Academic Affairs from 2000 until May 2002. He currently serves as the Joseph Butenas Professor of Medical Education and Dean of Medical Education at Georgetown. Dr. Mitchell is an expert in the field of adult and pediatric rheumatology as well as all aspects of medical education in America. In 2004, he was inducted into Mastership of the College – the highest honor bestowed only on 600 living members of the 150,000 member organization. In July 2005, he was named one of Washingtonian magazine's "Top Docs" for his work in pediatrics at Georgetown.

*Alicia Mundy, Wall Street Journal, Reporter*

Ms. Mundy, who joined the Wall Street Journal early 2008, has specialized in probing the links between FDA policy and lobbying efforts by drug-makers and other health care companies. Ms. Mundy was a New America Foundation fellow from 2003 through 2006, during which time she worked on a variety of media projects involving the pharmaceutical industry and the shortcomings of the

current regulatory process. Ms. Mundy is the author of *Dispensing With The Truth*, which describes deception at Wyeth-Ayerst (then a division of American Home Products) pertaining to the risks of the diet drug combination fen-phen. In her book, she reported on ghostwriting campaigns by Wyeth involving important obesity doctors, and revealed several conflicts of interest involving obesity doctors consulting and speaking for Wyeth, and conducting CME that supported the use of the company's newest diet drug.

*Edmund Pellegrino, MD, Professor Emeritus of Medicine and Medical Ethics, Kennedy Institute of Ethics, Georgetown University*

Dr. Pellegrino is Professor Emeritus of Medicine and Medical Ethics at the Kennedy Institute of Ethics and is Interim Director of the Center for Clinical Bioethics at Georgetown University. He has served as chairman of the President's Council on Bioethics in Washington, DC, John Carroll Professor of Medicine and Medical Ethics, and as Director of the Kennedy Institute of Ethics, the Center for the Advanced Study of Ethics at Georgetown University and the Center for Clinical Bioethics. Recently he completed a term on the UNESCO Bioethics Council. Dr. Pellegrino is the author of over 600 published items on medical science, philosophy, and ethics and is a member of numerous editorial boards. He is author of co-author of 23 books and is founding editor of the *Journal of Medicine and Philosophy*. Dr. Pellegrino received his B.S. degree from St. John's University and his MD from New York University. He served residencies in medicine at Bellevue, Goldwater Memorial, and Homer Folks Tuberculosis Hospitals, following which he was a research fellow in renal medicine and physiology at New York University. During Dr. Pellegrino's 60+ years in medicine and university administration, he has been departmental chairman, dean, vice chancellor and president.

*Mike Saxton, MEd, FACME, CCMEP, Consultant*

Mr. Saxton has been active in the CME/CPD profession for over 20 years. Most of his practice, like a recent three-year tenure building a new medical education support department at Pfizer, has been in the commercial support setting. He has worked as an advocate for transforming commercial support to a higher quality standard of education and independence while preserving recognition of industry's mutually aligned non-promotional interests in contributing to improved healthcare quality and safety. Recently, he left industry in order to more actively pursue reform through the formation of a non-profit foundation whose mission will relate to accelerating the transformation of continuing education in the health professions through developing a sustainable business model that effectively mitigates conflicts of interest risk and promotes the use of CPD (continuing professional development) to improve quality and patient safety as called for in several recent consensus reports.

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).

*Anthony Scialli, MD, Clinical Professor of Obstetrics and Gynecology, George Washington University School of Medicine*

Dr. Scialli has practiced medicine and taught residents and medical students for 35 years, most of which he has spent at Georgetown University as Professor and Director of the Residency Training Program in Obstetrics and Gynecology. Dr. Scialli is the author of many peer-reviewed articles and consumer articles, and has written several articles about hormone therapy and evidence-based medicine. Dr. Scialli has authored or edited six books, including a consumer book, *The National Women's Resource Center Book of Women's Health* (New York: William Morrow; 1999).

*Hanadi Shamkhani MD, RPh, Staff Internist, Kaiser-Permanente*

Dr. Shamkhani is a physician and pharmacist, currently working as a staff internist at the Prince Georges Medical Office Building in Kaiser Permanente of the Mid-Atlantic States (MAS). She has served on the Regional Pharmacy and Therapeutics Committee for Kaiser Permanente-MAS since 1997 and became Co-chair of that committee as well as Physician Director for Drug Utilization Management from 2005 to February 2010. In addition to this role, Dr. Shamkhani also served as the Director of Practitioner Performance Review and Oversight Department, which performed the peer review functions for the organization from 2000 to 2005.

*Joshua Sharfstein, MD, Principal Deputy Commissioner, U.S. Food and Drug Administration*

Dr. Sharfstein is the Principal Deputy Commissioner of the Food and Drug Administration and has served as the commissioner of health for the city of Baltimore. Under his leadership, the Baltimore Health Department and its affiliated agencies won multiple national awards for innovative programs. Dr. Sharfstein has also served as minority professional staff of the Government Reform Committee of the U.S. House of Representatives for Congressman Henry A. Waxman. Dr. Sharfstein is a graduate of Harvard Medical School and completed a combined residency program in pediatrics at Boston Children's Hospital and Boston Medical Center and a fellowship in general pediatrics at the Boston University School of Medicine. In 2008, Dr. Sharfstein was named a Public Official of the Year by Governing magazine.

*Julie Taitsman, MD, JD, Chief Medical Officer, US Department of Health and Human Services Office of Inspector General*

As Chief Medical Officer in the Office of Inspector General for the U.S. Department of Health and Human Services, Dr. Taitsman is an expert in oversight of the health care system, fraud and abuse, and conflict of interest and has lectured extensively on these topics. She previously served as a Senior Counsel in the Industry Guidance Branch of the Office of Counsel to the Inspector General. While at OIG, she was detailed to the Senate Finance Committee to serve as Special Counsel for Health and Science. Prior to joining the Office of Inspector General, she practiced health care law in Washington, DC, focusing on Medicare payment and coverage and regulation of drugs, biologics, and medical devices.

Dr. Taitsman earned a B.A. from Brown University in 1992, an M.D. from Brown University School of Medicine in 1996, and a J.D. from Harvard Law School in 1998. She completed the Preliminary Medicine Residency Program at Carney Hospital in Boston in 1999 and clerked for Judge Constance Baker Motley in the U.S. District Court for the Southern District of New York from 1999 to 2000.

*Paul Thacker, Senior Investigator, Office of Senator Grassley*

Mr. Thacker earned a biology degree at the University of California—Davis in 1997. In 2000, he completed journalism internships at *Audubon Magazine* and *Discover* and later joined the staff of *Environmental Science & Technology*, a publication of the American Chemical Society, which represents academic and industrial chemists. Mr. Thacker has written a series of exposés including the description of the tactics a chemical company used to minimize concerns about a chemical in their product and a story for *The New Republic* that exposed the science columnist for Fox News as a paid pundit for Big Tobacco. As an investigator on the United States Senate Finance Committee, Mr. Thacker continues to spearhead high-profile investigations in conflicts of interest in biomedical science.

*Stephen Willis, MD, Associate Dean of CME, Brody School of Medicine at East Carolina University; Executive Director, Eastern Area Health Education Center*

Dr. Willis is a Family Medicine physician and Associate Dean of CME and Distance Learning at the Brody School of Medicine at East Carolina University. He is also the Executive Director of the Eastern Area Health Education Center in Greenville, NC. Dr. Willis has extensive teaching and lecturing experience at all levels in the medical continuum. Dr. Willis is committed to providing a quality product in CME and performance improvement in ambulatory practice without reliance on commercial support.

*Robert Wittes MD, Physician-in-Chief Memorial Sloan-Kettering Cancer Center*

Dr. Wittes is a highly experienced medical oncologist and is physician-in-chief of Memorial Sloan-Kettering Cancer Center. Additionally, he has held several leadership positions at the National Cancer Institute and was Senior Vice President for Cancer Research at the Bristol-Myers Company between 1988 and 1990.

**Disclosures:**

Daniel Carlat, MD: Clearview Publishing (President); CME Newsletter (Dr. Carlat's lecture not included towards earning CME credit)

Glenn Demott, MS: No disclosures listed

Carl Elliott, MD, PhD: No disclosures listed

Michael Frisch, JD: No disclosures listed

Adriane Fugh-Berman, MD: Expert witness on behalf of plaintiffs in litigation regarding pharmaceutical marketing practices

Jeremy Greene, MD, PhD: No disclosures listed

Mark Helm, MD, MBA: Helm Benefit Design

Elissa Ladd, PhD, RN: No disclosures listed

Joel Lexchin, MD: No disclosures listed

Douglas Melnick, MD, MPH: Consulted for plaintiff's attorney in a case involving allegations of illegal marketing practices by a pharmaceutical company

Edmund Pellegrino, MD: No disclosures listed

Hanadi Shamkhani, MD, RPh: No disclosures listed

Joshua Sharfstein, MD: No disclosures listed

Julie Taitsman, JD, MD,: No disclosures listed

Paul Thacker: No disclosures listed

Stephen Willis, MD: No disclosures listed

Robert Wittes, MD: No disclosures listed

**Note:** Disclosures were not requested for Maureen Doyle-Scharff, MBA, FACME; Norman Kahn, MD; David Davis, MD; Mike Saxton, MEd; and Alicia Mundy because the Pros and Cons of Industry-Funded Education panel was not eligible for CME or CEU credit.

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