

Biographies (in alphabetical order)

Ernest R. Berndt, Ph.D.

Ernst R. Berndt is the Louis B. Seley Professor of Applied Economics at the MIT Sloan School of Management, and Co-Director of the Biomedical Enterprise Program at the Harvard-MIT Division of Health Sciences and Technology. He is also the Director of the National Bureau of Economic Research Program on Technological Progress and Productivity Measurement, and Co-Director of the Center for Biomedical Innovation at MIT. Until recently, he served as Chairperson of the Federal Economic Statistics Advisory Committee, an interagency advisory panel established by the Bureau of Economic Analysis, the Census Bureau and the Bureau of Labor Statistics. He has served on the editorial boards of numerous peer-reviewing journals; currently he is a member of the editorial board of Health Affairs. Professor Berndt earned a Ph.D. degree in economics from the University of Wisconsin - Madison in 1972, and was awarded an honorary doctorate for his research on productivity measurement from Uppsala University in Sweden in 1991. Much of Professor Berndt's recent research has focused on price, output and outcomes measurement in the health care industries, and on regulatory policies at the U.S. Food and Drug Administration.

Bruce Burlington, M.D.

Bruce Burlington is Executive Vice President for Quality, Regulatory, Safety, Compliance and Audit at Wyeth Pharmaceuticals located in Collegeville, Pennsylvania. In this position, he has responsibility for the Regulatory Affairs, Safety Surveillance, Quality Operations, Compliance Operations, and Audit Departments all on a worldwide basis. These responsibilities span the company's human prescription products (pharmaceuticals, bio-pharmaceuticals, medical devices and vaccines) and (for the Quality, Compliance, and Audit Departments) also include infant formula and OTC drugs. As a member of the corporate Law and Regulatory Committee as well as both the Wyeth Research and Wyeth Pharmaceutical Management Committees, he is broadly involved in Wyeth's general management.

Graduated with an M.D. from Louisiana State University School of Medicine at New Orleans in 1976, Bruce undertook clinical training at the University of Colorado earning board certification in Internal Medicine and Infectious Diseases. He served on the University's faculty from August 1979 through October 1981.

Bruce moved to Wyeth in March 1999 after seventeen years at the United States Food and Drug Administration. While at FDA, he was a research fellow in the Center for Biologics (the Viral Vaccine program) and then headed the Investigational New Drug Division during the development of many key biotechnology products (Tissue Plasminogen Activator, Alfa Interferon, Erythropoietin, GCSF, recombinant vaccines, etc.). He moved to the New Drug Evaluation program from 1988 through 1993. Subsequent to the generic drug scandals, he spent one year (as a collateral assignment) heading and reestablishing the credibility of the Generic Drugs program and then became Deputy Center Director for Medical Affairs. From 1993 to 1999 he managed FDA's Center for Medical Devices and Radiological Health, overseeing the U.S. government's regulatory programs for medical devices, in vitro diagnostic products, radiological health, and mammography quality.

During his career at the FDA Bruce received numerous awards for creative management and exceptional performance. He also continued a part-time medical practice and was a teaching preceptor in Emergency Medicine.

Judith A. Cahill

As Executive Director of the Academy of Managed Care Pharmacy, Judy Cahill has responsibility for policy creation and implementation, administrative operations, and overall staff leadership of the Academy of Managed Care Pharmacy (AMCP). The Academy is a professional society with over 4,800 members nationwide which is dedicated to the continuing professional development of pharmacists and other health care practitioners engaged in the practice of pharmacy in managed care settings.

Judy has been working in the dynamic area of managed health care for the past 20 years. For 11 years she helped direct the activities of the Group Health Association of America, the leading trade association representing health maintenance organizations in the United States. Her area of responsibilities included policy development, medical management issues embracing quality measurement and management, and development of education programs, publications, and research projects. Prior to her duties with GHAA, Ms. Cahill served as contracting officer for the HMOs that participated in the United States Federal Employees Health Benefits Program.

Ms. Cahill holds a Bachelor of Arts degree from LeMoyne College, a Masters of Arts degree from the University of Cincinnati, and certification as an Employee Benefits Specialist from the Wharton School of Business. She serves on several editorial advisory boards and Boards of Directors for organizations dedicated to serving the pharmacy profession.

Perry Cohen, Ph.D.

Perry Cohen is an active participant and leader on the national level in advocacy activities for Parkinson's issues. He is Project Director for the Parkinson's Pipeline Project, which he initiated to provide the patient's perspective to clinical researchers and sponsors of new therapies. Prior to diagnosis with PD in May 1996, Dr. Cohen was a planning and evaluation consultant in the health industry for public health agencies, health insurance plans, medical groups and academic research centers. He has an MS and a Ph.D. in Organizational Development from MIT, Sloan School of Management; and a BS in Management Science and Math from Carnegie-Mellon University.

Diane Edquist Dorman

Ms. Dorman currently serves as Vice President for Public Policy for the National Organization for Rare Disorders (NORD), where she develops and maintains relationships with federal agencies, including the National Institutes of Health, Food and Drug Administration, and the Centers for Medicare and Medicaid Services, the United States Congress, the biotechnology and pharmaceutical industries, and other healthcare-related agencies.

Her efforts include work with other patient organizations and coalitions to accomplish initiatives that benefit people with rare diseases. Technical assistance and legislative analysis are provided to NORD's member agencies on government-related matters, as well as the training of staff and volunteers of member organizations.

In August, 2001, Ms. Dorman was instrumental in the introduction of the *Rare Diseases Act*, sponsored by Senators Edward Kennedy and Orrin Hatch and later introduced in the House of Representatives by Representatives John Shimkus (R-IL) - *The Rare Diseases Act* P.L. 107-280 - and Mark Foley (R-FL) - *The Rare Diseases Orphan Product Development Act* (P.L. 107-281). In just 15 months, with the help of 136 organizations and thousands of patients and family members across the country, this landmark legislation was signed into law on November 6, 2002.

Dorman was also influential in the introduction of House Concurrent Resolution 147, introduced by Representative Mark Foley commemorating the 20th Anniversary of the *Orphan Drug Act* and the National Organization of Rare Disorder (NORD). The Concurrent Resolution was presented to NORD President, Abbey Meyers, on May 19, 2003.

Today, Ms. Dorman continues to increase NORD's influence in Washington, DC. Her work with all stakeholders has raised awareness of the issues affecting the rare disease community, including the need for increased basic and translational research into rare diseases, and continuing access to life-saving therapies for the entire rare disease community.

Prior to her work at NORD, Ms. Dorman worked with the Generic Pharmaceutical Industry Association as Director of Public Affairs. There, she planned and conducted public relations programs designed to create and maintain a favorable public image. Her work included establishing and maintaining cooperative relationships with representatives of community and consumer organizations, public interest groups and journalists representing print and broadcast media.

Carole Redding Flamm, MD, M.P.H.

Carole Redding Flamm is Senior Medical Director in the Office of Clinical Affairs at the Blue Cross and Blue Shield Association.

Dr. Flamm's responsibilities at the Association include improving the safety and health outcomes of episodes of care experienced by Blue Cross and Blue Shield Plan members, through collaboration with the providers to whom their care is entrusted. She also manages the many quality based Blue Cross and Blue Shield Association network initiatives.

Prior to her current position, Dr. Flamm was Associate Director of the Association's Technology Evaluation Center (TEC). Prior to her work at the Association, Dr. Flamm was an instructor in radiology at Harvard Medical School and also served as an Associate in Radiology at Beth Israel Hospital in Boston, Massachusetts.

Dr. Flamm received her Medical Degree from the University of Pennsylvania, and holds a Master's Degree in Public Health from Harvard.

RADM Steven Galson, M.D., M.P.H.

RADM Steven Galson was named Director of the Center for Drug Evaluation in July, 2005. He provides leadership for the Center's broad national and international programs in pharmaceutical regulation. RADM Galson began his PHS career as an epidemiological investigator at the Centers for Disease Control and has held senior-level positions at the Environmental Protection Agency, Department of Energy, and the Department of Health and Human Services. Prior to his arrival at FDA, RADM Galson was the Director of the Office of Science Coordination and Policy, Office of Prevention, Pesticides and Toxic Substances, at the EPA. Dr. Galson joined FDA in April 2001 as the CDER Deputy Director. RADM Galson is the recipient of numerous PHS awards, most recently the Outstanding Service Medal for his leadership and management of CDER while serving as Acting Center Director from November 2001 to February 2002. RADM Galson holds a B.S. from Stony Brook University, an M.D. from Mt. Sinai School of Medicine and a MPH from the Harvard School of Public Health. He is

Board Certified in Preventive Medicine & Public Health and Occupational Medicine.

Jesse L. Goodman, M.D., M.P.H.

Dr. Goodman is the Director of FDA's Center for Biologics Evaluation and Research (CBER) which oversees a broad range of medical, public health and policy activities concerning the development and assessment of vaccines, blood products, tissues, and related devices and novel therapeutics including cellular and gene therapies. He first came to FDA in late 1998 from the University of Minnesota where he had joined the Faculty in 1985 and most recently served as Professor of Medicine and Director of the Division of Infectious Diseases. A graduate of Harvard College, he received his M.D. at Albert Einstein, did residency and Fellowship training at the Hospital of the University of Pennsylvania and at UCLA (where he was also Chief Medical Resident), obtained a MPH at the University of Minnesota, and is Board Certified in Internal Medicine, Oncology and Infectious Diseases. He trained in the virology laboratory of Jack Stevens at UCLA and has had an active laboratory program in the molecular pathogenesis of infectious diseases. In 1995, his NIH funded laboratory isolated the etiologic agent of a new disease, human granulocytic ehrlichiosis (HGE) and has since characterized fundamental events involved in infection of leukocytes, including its cellular receptor. He has been an active clinician, investigator, administrator, and educator, and is the author of numerous peer reviewed scientific publications. He is Senior Editor of the book "Tick Borne Diseases of Humans" to be published by the ASM Press in 2005 and is a Staff Physician and Infectious Diseases Consultant at the NIH Clinical Center and the National Naval Medical Center/Walter Reed Army Medical Center, as well as Adjunct Professor of Medicine at the University of Minnesota and at Howard University. He co-chaired both the FDA Task Force and the U.S. Government Interagency Task Force on Antimicrobial Resistance. At FDA, and representing FDA within the government and to the public, he is active in a wide variety of clinical and public health issues including bioterrorism preparedness and response, emerging infectious disease threats (e.g. West Nile Virus, avian influenza, SARS), product

development, blood, tissue and vaccine safety and risk management. In these activities, he has worked closely with CDC, NIH and other HHS components and the private sector, and put into place an interactive team approach to emerging threats: this model was used successfully in the highly collaborative development and rapid implementation of nationwide donor screening of the US blood supply for West Nile Virus. He has received honors and awards including election to the American Society for Clinical Investigation (ASCI) and has served on a number of committees and review panels for groups such as the NIH, CDC, WHO, the Minnesota Department of Health and the National Academy of Sciences/Institute of Medicine.

Scott Gottlieb, M.D.

Dr. Scott Gottlieb is the Deputy Commissioner for Medical and Scientific Affairs at the U.S. Food and Drug Administration and a former senior official at the Centers for Medicare and Medicaid Services.

A practicing physician, from 2003-2004, Dr. Gottlieb served as a senior advisor to the FDA Commissioner and as the Agency's Director of Medical Policy Development, leaving in the spring of 2004 to work on implementation of the new Medicare Drug Benefit as a Senior Adviser to the Administrator of Medicare and Medicaid Services.

As the FDA's Deputy Commissioner for Medical and Scientific Affairs, Dr. Gottlieb is a senior advisor to Dr. Andrew von Eschenbach on all major agency matters including regulations, policy and administrative programs. His office works with all of the FDA's centers on implementing and coordinating the agency's regulatory and administrative policies aimed at advancing the public health.

Before re-joining FDA, Dr. Gottlieb worked as a Resident Fellow at the American Enterprise Institute (AEI), a prominent Washington, DC-based think tank and as an American medical correspondent for the British Medical Journal and a writer for Forbes Magazine.

The author of more than 300 policy and medical articles, Dr. Gottlieb is a noted authority on issues pertaining to health policy, medical technology, and on seeking improvements in the public health through innovation in technology, medical practice and healthcare delivery.

Dr. Gottlieb is a graduate of Wesleyan University, in Middletown, Connecticut and the Mount Sinai School of Medicine in New York. He completed residency training in Internal Medicine at the Mount Sinai Hospital in New York. Dr. Gottlieb practiced medicine as an attending physician at Stamford Hospital in Connecticut where he was an Internist on the hospital's inpatient medical wards.

Mary Gustafson, M.P.H.

Mary Gustafson is Senior Director, Global Regulatory Policy, Plasma Protein Therapeutics Association (PPTA). Prior to joining PPTA, Ms. Gustafson served as Senior Director, Regulatory Affairs at Nabi Biopharmaceuticals, Boca Raton, FL and in regulatory positions at the U.S. Food and Drug Administration (FDA). At FDA, she directed the Division of Blood Applications, Office of Blood and Research and Review, Center for Biologics Evaluation and Research, as well as holding earlier positions in Biologics compliance and product certification. Ms. Gustafson has a MS degree in Pathology, is certified as a medical technologist and specialist in blood banking by the American Society for Clinical Pathology, and quality manager and auditor by the American Society for Quality.

Deborah Henderson, R.N., M.S.N.

Since October 1994, Ms. Henderson has been Director of the Office of Executive Programs (OEP) in CDER. The Office of Executive Programs houses a variety of Center-wide staff functions, including the Executive Secretariat, the Advisors and Consultant staff, the international program staff, the quality assurance staff, as well as the administrative staff support to the Office of the Center Director. OEP also include provides project management support for Centerwide initiatives, organizational development, and CDER strategic planning activities.

Ms. Henderson began her FDA career in the Center for Biologics Evaluation and Research, FDA, in 1988 serving first as the Special Assistant to the Director and later as Associate Director for Policy in the Office of Therapeutics Research and Review. From 1977 until 1988, she worked at the National Institutes of Health: six years as a critical care nurse and later as the Special Assistant to the Director of the National Institute of Allergy and Infectious Diseases. A Washington, D.C. native, Ms. Henderson received her nursing education and training at the Catholic University of America.

Jeanne Ireland

As Director of Public Policy since 2002, Jeanne Ireland leads the Foundation's advocacy efforts aimed at eradicating pediatric AIDS, expanding HIV/AIDS care and treatment globally, and accelerating the discovery of new treatments for other serious and life-threatening pediatric illnesses. From 2001-2002, Ms. Ireland was a fellow with the Robert Bosch Foundation in Berlin, Germany, where she worked in the Bundestag and for the European Academy for Women in Politics and Business on improving German work/life policies. From 1997-2001, as minority staff director for the Senate Health and Education Committee's Subcommittee on Children and Families she advised Senator Chris Dodd on child care and health issues. In that role, she was involved in negotiating the Food and Drug Administration Modernization Act of 1997 and the inclusion of incentives for pediatric drug testing. Prior to that, Ms. Ireland spent four years in a variety of positions at the National Institutes of Health and the Maternal and Child Health Bureau. She received her B.A. from the University of Virginia and A.M. from the University of Chicago.

Kenneth I Kaitin, Ph.D.

Dr. Kaitin is Director of the Tufts Center for the Study of Drug Development, an academic drug policy research group providing strategic information to help drug developers, regulators, and policy makers improve the quality and efficiency of the drug development process. He is also Associate Professor of Medicine at Tufts University School of Medicine. In addition, he serves on the faculty of the European Center for Pharmaceutical Medicine at the University of Basel. Dr. Kaitin received a B.S. from Cornell University and an M.S. and Ph.D. in pharmacology from the University of Rochester.

Dr. Kaitin conducts research, lectures, and writes on pharmaceutical development, regulation, and public policy. He has written extensively on factors that contribute to the slow pace and high cost of pharmaceutical R&D and the impact of regulatory and legislative initiatives to speed new drug development and review. Dr. Kaitin has provided public testimony before the U.S. Congress in hearings on pharmaceutical innovation and FDA reform, and he has worked closely with the U.S. Council on Competitiveness. He is on the Board of Directors of the New England Institute for Health Care Research and Innovation, and he served on the Center for Strategic and International Studies' bioterrorism task force, "National Strategy for Anti-Biothreat Vaccines, Therapeutics, and Diagnostics." Dr. Kaitin is a former President of the Drug Information Association (1997-98) and Editor-in-Chief of the *Drug Information Journal* (2002-04). He serves on the editorial boards of the *American Journal of Therapeutics*, *Clinical Research and Regulatory Affairs*, *Drug Information Journal*, *Drug Discovery and Development*, and the *Food and Drug Letter*.

Arthur A. Levin, M.P.H

Arthur A. Levin is Director of the Center for Medical Consumers, a New York City based non-profit organization committed to informed consumer and patient health care decision-making, patient safety, evidence-based, high quality medicine and health care system transparency. It receives no funding from the drug, device or health care industry.

Mr. Levin was a member of the Institute of Medicine's (IOM) Committee on the Quality of Health Care that published the "*To Err is Human*" and "*Crossing the Quality Chasm*" reports. He also served as a member of the Institute of Medicine committee that evaluated the federal quality effort and made recommendations to Congress in its' report "*Leadership Through Example*."

He was recently appointed to the Institutes' Board on Health Care Services which has been responsible for overseeing the IOM's decade long effort to improve the quality and safety of America's health care system. Levin is also a member of the IOM Board of Health Care Services, one of eight boards that direct the work of the IOM.

Mr. Levin serves as a member of the NCQA Committee on Performance Measures that is charged with developing performance measures for health plans and most recently, for physician practices. He also is a member of the NCQA Consumer Advisory Committee.

Levin has been a long-time member of the FDA's Consumer Nominating Workgroup that recommends consumer representatives for FDA Advisory Committees and has served as a guest expert on risk management at FDA Drug Advisory Committee meetings. He is the consumer member on the FDA's Drug Safety and Risk Management Advisory Committee (DSaRM).

Levin earned his Masters of Public Health degree from Columbia University School of Public Health and a Bachelor of Arts degree in Philosophy from Reed College.

Sara Radcliffe, M.P.H.

Sara Radcliffe is the Managing Director for Scientific and Regulatory Affairs at the Biotechnology Industry Organization (BIO). BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations in the United States and 31 other nations. At BIO, Ms. Radcliffe has lead responsibility for developing and implementing strategic BIO responses to scientific and regulatory issues that affect the ability of BIO's human healthcare focussed companies to research and develop products, and to bring these products to market. Before joining BIO, Ms. Radcliffe was Senior Director, Biologics & Biotechnology, and Assistant Vice-President, Preclinical Drug Safety Evaluation, at the Pharmaceutical Research and Manufacturers of America (PhRMA). She also worked for the Alliance and Technology Group at SmithKline Beecham Pharmaceuticals as a Research and Development Policy Analyst, where her work focussed on evaluation and communication of the promise, ethics, and impact of rapidly-developing technologies in DNA Research, including Pharmacogenetics.

Alison Rein, M.S.

Alison Rein is the Assistant Director of Food & Health Policy at the National Consumers League (NCL). Founded in 1899 to bring consumer power to bear on marketplace and workplace issues, NCL is the nation's oldest consumer organization. Ms. Rein designs and coordinates campaigns and other activities around NCL's priority issues, including food safety and nutrition, medication safety, and health care quality. In the last year, she has expanded NCL's involvement as a consumer stakeholder in the national discussion about emerging health technologies.

Prior to joining NCL, Ms. Rein served as a health care consultant to a number of private and non-profit organizations, for which she conducted strategic evaluations, market studies, and research efforts aimed at evaluating the cost-effectiveness of numerous drug, biologic, and device interventions. She holds a masters degree in public policy analysis from the University of Rochester, and has co-authored several articles published in peer-reviewed medical journals.

Ellen V. Sigal, Ph.D.

Ellen V. Sigal, PhD, is founder and Chairperson of Friends of Cancer Research ("Friends"), a Washington, DC based non-profit organization. Friends is dedicated to accelerating the nation's progress toward prevention and treatment of cancer by mobilizing public support for cancer research funding and providing education on key public policy issues.

Dr. Sigal serves on the National Cancer Institute Board of Scientific Advisors, the National Institutes of Health prestigious Director's Council of Public Representatives, the National Institutes of Health Foundation Board chairing its Public-Private Initiatives Committee, the American Society of Clinical Oncology Foundation Board, the American Association for Cancer Research Foundation Board, the Johns Hopkins Cancer Center Advisory Council, the Duke University Cancer Center Board of Overseers, and the Howard University Cancer Center Board of Visitors.

She was a Presidential Appointee to the National Cancer Advisory Board from 1992-1998 chairing its Budget and Planning Committee which oversees the federal cancer budget.

Dr. Sigal was honored in 2004 by the Association of American Cancer Institutes, Research!America, George Washington University Cancer Institute, International Spirit of Life Foundation, and Washingtonian magazine as a 2004 Washingtonian of the Year. In 2002 she received the American Society of Clinical Oncology Special Recognition Award, in 1999 the Sidney Kimmel Cancer Center National Leadership Award, and in 1998 the American Association for Cancer Research National Leadership Award.

Hugh H. Tilson, M.D., Dr.P.H.

Hugh Tilson M.D. (Washington University, St. Louis, Missouri 1964), DrPH (Harvard School of Public Health 1972) is a practicing epidemiologist and outcomes researcher, whose career in public health and preventive medicine spans more than 35 years. Fifteen years of public service included duties as a U.S. Army Preventive Medicine Officer in Germany; Consultant to the U.S. Office of Economic Opportunity, National Center for Health Services Research, and Veterans Administration; Local Public Health Officer and Human Services Director for Multnomah County (Portland), Oregon (NACHO President, 1976); and State Public Health Director for North Carolina. During fifteen years in the multinational pharmaceutical industry, for the Wellcome Foundation, he is credited for introducing many epidemiologic principles and innovations ... public health in the private sector. Upon his retirement from GlaxoWellcome in 1996, he joined the full time clinical faculty of UNC School of Public Health in Chapel Hill. He is Adjunct Professor of Social Medicine at UNC, Medicine at Duke, and Pharmacy at UNC. He is an advisor to government and industry in health outcomes, drug safety, and evidence based health policy, including, most recently public health preparedness. He was Founding Co-President of the International Society for Pharmacoepidemiology (ISPE) and a Founding Member of the International Society for Pharmacoconomics and Outcomes Research (ISPOR) and of the American Academy of Pharmaceutical Physicians, and has recently served as Chair of the Committees for Bylaws and Policies for all three. He was a member of the Council for International Organisations for the Medical Sciences (CIOMS) working groups on Drug Safety from 1990 to 2005 and continues as an advisor to the WHO Collaborating Centres. In the US, he chairs the National Steering Committee for the Centers for Education and Research on Therapeutics (CERTs) program for AHRQ. He is a Liaison member of the Board on Health Promotion and Disease Prevention, most recently a liaison to the IOM Clinical Research Roundtable and Chair of the IOM Committee on the Safety of Therapeutic Devices in Children. He is currently Chair of the IOM Study Committee on Needle Exchange and has been designated a Lifetime National Associate of the National Academies of Science.

Allen J. Vaida, Pharm.D. FASHP

Allen J. Vaida is the Executive Director for the Institute for Safe Medication Practices (ISMP) in Huntingdon Valley, PA. He previously served as Vice President of Clinical Operations (Chief Operating Officer) at Mercy Suburban Hospital in Norristown, PA. Prior to his appointment as Vice President in 1995, Vaida held the positions of Director of Pharmacy and then Assistant Vice President and Director of Pharmacy at Suburban General Hospital in Norristown, PA. Dr. Vaida has served on various committees and as a board member for several healthcare organizations including as a Trustee for ISMP from its incorporation in 1994 through his employment as Executive Director in 2000. Vaida served on the United States Pharmacopeia's Safe Medication Use Expert Committee from 2000 through 2005 and is Clinical Assistant Professor at the University of the Sciences in Philadelphia, Assistant Adjunct Professor at Temple University School of Pharmacy, Adjunct Associate for the Centers for Health Policy and Primary Care and Outcomes Research at Stanford University and Stanford University School of Medicine, and adjunct faculty for the Executive Patient Safety Fellowship offered through Virginia Commonwealth University, Richmond, VA. He currently serves on the Advisory Board of the Maryland Patient Safety Center. He has given professional presentations on hospital and pharmacy systems and management, error prevention strategies, healthcare outcomes, integrated systems and interdisciplinary collaboration. Vaida has published numerous articles in the pharmacy literature and served as a script and production consultant for the videos, *Reducing Medication Errors through Failure Mode and Effects Analysis* and *Pharmaceutical Care in Oncology Therapy: Caring Enough to Understand*. He has made numerous presentations on

medication error reduction strategies and the importance of nonpunitive reporting programs. Dr. Vaida is a past president of the Pennsylvania Society of Health-System Pharmacists and a recipient of the Pharmacist of the Year Award in Pennsylvania and the Jonathan Roberts Award from the Delaware Valley Society of Health-System Pharmacists. He was elected as a Fellow of the American Society of Health-System Pharmacists in 1995. Vaida received a Bachelor of Science in Biology from the University of Scranton, a Bachelor of Science in Pharmacy from the Philadelphia College of Pharmacy and Science and a Doctor of Pharmacy degree from the University of Minnesota.

Bill Vaughan

Bill Vaughan is currently Senior Policy Analyst in the health sector for Consumers Union, the non-profit, independent publisher of *Consumer Reports*. Starting in 1965 he worked for various Members of the House of Representatives' Ways and Means Committee, and retired in 2001 as Health Subcommittee Staff Director for the Minority. Between 2003 and May 2005 he was Director of Government Relations for Families USA, a national health advocacy organization.

Andrew C. von Eschenbach, M.D.

Andrew C. von Eschenbach, M.D., is the 12th Director of the National Cancer Institute (NCI) since its creation in 1937. In September, 2005 he was named Acting Commissioner of the Food and Drug Administration. A nationally recognized urologic surgeon, Dr. von Eschenbach's distinguished career as a key leader in the fight against cancer spans nearly three decades.

Prior to accepting the appointment to lead the NCI in January 2002, Dr. von Eschenbach served as Executive Vice President and Chief Academic Officer of the University of Texas M.D. Anderson Cancer Center in Houston, leading a faculty of nearly 1,000 cancer researchers and clinicians. At M.D. Anderson he also served as Vice President for Academic Affairs and held the distinguished Roy M. and Phyllis Gough Huffington Clinical Research Distinguished Chair in Urologic Oncology.

Dr. von Eschenbach, as founding director of the Prostate Cancer Research Program, was instrumental in fostering integrated research programs in the biology, epidemiology, prevention, and treatment of prostate cancer at M.D. Anderson. He also directed the Genitourinary Cancer Center there. Dr. von Eschenbach joined M.D. Anderson as a urologic oncology fellow in 1976 and was invited to join the faculty a year later. Just six years later - in 1983 - he was named chairman of the Department of Urology. Other positions held at M.D. Anderson include Consulting Professor of Cell Biology and Professor of Urology.

Dr. von Eschenbach, himself a cancer survivor, has had an impact on the fight against cancer that extends beyond the clinical and academic communities. He is a founding member of C-Change and was president-elect of the American Cancer Society at the time of his appointment to the NCI. In addition, he has made significant contributions to the scientific literature -- more than 200 articles, books, and book chapters. Dr. von Eschenbach has also served as an editorial board member of several leading journals and on several organizational boards.

Many influential organizations have recognized Dr. von Eschenbach for his leadership and accomplishments, among them the American Medical Writers Association, the American Urological Association, and the Uniformed Services University of Health Sciences. Dr. von Eschenbach has also been included in "The Best Doctors in America" publications, received the Medical Award of Excellence from Cancer Counseling, the Achievement Awards from the 100 Black Men of Metropolitan Houston and Partners in Courage for his significant contributions to prostate cancer programs, and the Julie Rogers "Spirit of Love" Award for demonstrating unparalleled dedication, commitment, and spirit in the fight against cancer.

A native of Philadelphia, Dr. von Eschenbach earned a B.S. from St. Joseph's University in Philadelphia in 1963 and his medical degree from Georgetown University School of Medicine in 1967. Dr. von Eschenbach completed residencies in general surgery and urology at Pennsylvania Hospital in Philadelphia and then was an instructor in urology at the University of Pennsylvania School of Medicine. He also served as a Lieutenant Commander in the U.S. Navy Medical Corps.

Susan C. Winckler, RPh, Esq

Susan C. Winckler, RPh, Esq, is the Vice President for Policy and Communications and Staff Counsel for the American Pharmacists Association, the first-established and largest national professional society of pharmacists headquartered in Washington, DC. In that capacity, she is responsible for coordinating the Association's legislative, regulatory and private sector advocacy agenda and communication programs. Winckler serves as the primary spokesperson for the Association for media interviews, and is the senior lobbyist for the Association on Capitol Hill. In twelve years with APhA, she has served the profession in various capacities, including Group Director of Policy and Advocacy and Director of Practice Affairs (with responsibility for managing issues affecting pharmacist practitioners in all practice settings).

Prior to joining APhA, Winckler directed the implementation of the Iowa Medicaid Drug Prior Authorization Program for the Unisys Company, and worked for the Iowa Pharmacists Association (now the Iowa Pharmacy Association) and a community pharmacy in Iowa. Winckler is a graduate of the University Of Iowa College Of Pharmacy and the Georgetown University Law Center, *magna cum laude*. Winckler served as the APhA/National Council of State Pharmacy Association Executives (NCSPA) Executive Resident in Association Management with the North Carolina Pharmaceutical Association and the American Pharmaceutical Association (now the American Pharmacists Association). Winckler is a licensed pharmacist and admitted to the bar in the Commonwealth of Virginia. In June 2003, Winckler received The Distinguished Young Alumni Award from the University of Iowa Alumni Association, an award granted to University of Iowa graduates for significant accomplishments in business or professional life. Winckler serves on the Board of Directors for the American Society for Pharmacy Law.

Janet Woodcock, M.D.

Deputy Commissioner for Operations and Chief Operating Officer, FDA. She is responsible for overseeing Agency operations and cross-cutting regulatory and scientific processes at FDA. Dr. Woodcock served as Director, Center for Drug Evaluation and Research at FDA 1994-2005. She previously served in other positions at FDA including Director, Office of Therapeutics Research and Review and Acting Deputy Director, Center for Biologics Evaluation and Research. Dr. Woodcock received her M.D. from Northwestern Medical School, and completed further training and held teaching appointments at the Pennsylvania State University and the University of California in San Francisco. She joined FDA in 1986.

Raymond L. Woosley, M.D., Ph.D.

Raymond L. Woosley earned a Ph.D. in Pharmacology from the University of Louisville and an M.D. from the University of Miami. Dr. Woosley specialized in Internal Medicine and Clinical Pharmacology at Vanderbilt University where he rose to the rank of Professor of Medicine. At Georgetown University he served as Chairman of the Department of Pharmacology and in 2000 was appointed Associate Dean for Clinical Research. In 2001 he became Vice President for Health Sciences at the University of Arizona and Dean of the College of Medicine. In January of 2005 he assumed the position as President of The Critical Path Institute (C-Path), a non-profit corporation formed by the Food and Drug Administration, SRI, International and the University of Arizona to accelerate the development of safe innovative medicines. Since 1999, he has directed one of seven federally funded Centers of Education and Research on Therapeutics (CERT).

Dr. Woosley's research has been published in over 260 publications and has investigated the basic and clinical pharmacology of drugs for the drug treatment of arrhythmias and the cardiac toxicity of drugs. His research discovered the mechanism of the toxicity of the antihistamine Seldane that contributed to its subsequent removal from the market. For his contributions to medicine, he received the Rawls-Palmer Award from the American Society of Clinical Pharmacology and Therapeutics and the FDA Commissioner's Special Citation for his work to advise the agency on the toxicity of dietary supplements containing ephedra. In addition, Dr. Woosley is a Past-President of the Association for Medical School Pharmacology and the American Society for Clinical Pharmacology and Therapeutics. His current research is on the prevention of adverse drug interactions.

William A. Zellmer, M.P.H

William A. Zellmer, M.P.H., is Deputy Executive Vice President of the American Society of Health-System Pharmacists (ASHP), a professional association that represents pharmacists who perform the full array of pharmacy functions in hospitals and health systems, including practice managers, frontline practitioners, and specialized clinical pharmacists who serve both inpatients and ambulatory patients. He received his pharmacy education at the University of Wisconsin and earned a Master of Public Health degree from Johns Hopkins University. His responsibilities at ASHP include strategic planning, professional policy development, government affairs, public relations, and international affairs. He has a special interest in applying the resources of a professional society of pharmacists to address the most critical societal issues related to the appropriate use of medicines.

Diana Zuckerman, Ph.D.

Diana Zuckerman is the President of the National Research Center for Women & Families, a nonpartisan, nonprofit research and education organization that works to improve policies and programs that affect the health and safety of women, children, and families.

Dr. Zuckerman received her Ph.D. in psychology from Ohio State University and was a post-doctoral fellow in epidemiology and public health at Yale Medical School. She started her career as a faculty member at Vassar College, joined the faculty at Yale University, and subsequently left Yale to direct a research project at Harvard University.

From 1983 to 1993, Dr. Zuckerman worked as a Congressional staffer in the U.S. Congress, working for the House subcommittee that had oversight jurisdiction over the U.S. Department of Health and Human Services, including the Food and Drug Administration. She was responsible for more than a dozen Congressional investigations and hearings on a wide range of health and safety issues. In 1993, she went to the U.S. Senate, heading up the health staff for the Senate Committee on Veterans Affairs, chaired by Sen. Jay Rockefeller.

In 1995, Dr. Zuckerman served as a senior policy advisor in the White House, working for the First Lady and the Office of Science and Technology Policy. Since 1996, she has served in leadership positions at non-profit organizations, and has been president of the National Research Center for Women & Families since 1999.

Dr. Zuckerman's work has resulted in news coverage on *ABC, CBS, NBC, CNN, Fox News, public television, 60 Minutes, 20/20, National Public Radio, The New York Times, The Washington Post, The Washington Times, Los Angeles Times, Boston Globe, USA Today, Detroit Free Press, Washington Times, New York Daily News, Newsweek, Time, U.S. News and World Report, Family Circle, the New Yorker* and many other newspapers, magazines, and radio programs. In addition, she is the author of four books, several book chapters, and dozens of articles in academic journals and national newspapers.