Building Effective Partnerships
FDA Public Meeting

Panelist Biographies

Jane Henney
Robert Buchanan
Victoria Durant-Gonzalez
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David Lineback
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JANE E. HENNEY, M.D.
Commissioner of Food and Drugs
Food and Drug Administration

Dr. Henney began her tenure as Commissioner of the Food and Drug Administration (FDA) in November of 1998. Prior to that, she served as the first Vice President of the University of New Mexico Health Sciences Center from 1994 to 1998. Before joining the University, Dr. Henney served as the Deputy Commissioner for Operations at FDA from 1992 to 1994. Dr. Henney's other past academic administrative positions have included Vice Chancellor for Health Programs and Policy at the University of Kansas, and Acting Director of the University of Kansas Mid America Cancer Center from 1985 to 1992. She also served as Interim Dean of the School of Medicine at the University of Kansas from 1987 to 1989. From 1976 to 1985, Dr. Henney held various positions at the National Cancer Institute (NCI) of the National Institutes of Health. From 1980-1985, Dr. Henney was Deputy Director of the NCI.

In addition to being an active member of many professional societies, Dr. Henney has been the President of the United States Pharmacopeial Convention, a member of the Advisory Committee to the Director for the National Institutes of Health, a member of the National Advisory Research Resources Council, and a member of the American Cancer Society National Board of Directors. She has served as a member of the Board of Directors of the Lovelace Respiratory Institute, the Kansas Health Foundation, and the Kansas State University Cancer Center. Dr. Henney also has served on an Advisory Committee for The Commonwealth Fund and as a consultant to the W.K. Kellogg Foundation. She has also served as a member of the Board of Trustees at Manchester College.

Dr. Henney is a graduate of Indiana University School of Medicine and Manchester College. She completed her medical internship at St. Vincent's Hospital, and her residency at Georgia Baptist Hospital. Dr. Henney was a Fellow in Medical Oncology at M.D. Anderson Hospital and Tumor Institute, and completed graduate medical work at the Cancer Therapy Evaluation Program at NCI. She has also completed management training at the John F. Kennedy School of Government at Harvard University.

In addition to other distinguished honors, Dr. Henney was recently given an Honorary Fellowship from the American College of Healthcare Executives. She also received the Indiana University Medical School Distinguished Alumni Award in 1998, the Manchester College Alumni Award in 1996, the M.D. Anderson Cancer Center Distinguished Alumnus Award, and was a member of the Leadership New Mexico Inaugural Class in 1996-1997. Dr. Henney received the Public Health Service Commendation Medal in 1979 and 1981, and the Commissioner's Special Citation in 1994. Dr. Henney has also received the Jacobs Institute's Excellence in Women's Health Award, the Public Health Leadership Award from the National Organization for Rare Disorders, and the George Crile Award from the International Platform Association.

ROBERT L. BUCHANAN, PH.D.
Senior Science Advisor
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration

After receiving his B.S., M.S. M.Phil., and Ph.D. degrees in Food Science from Rutgers University and post-doctoral training in mycotoxicology at the University of Georgia, Dr. Buchanan has spent the past 25 years teaching and conducting research in food safety, first in academia, then with the USDA Agricultural Research Service, and most recently as the Lead Scientist for the FDA Food Safety Initiative. His scientific interests are diverse, and include extensive experience in predictive microbiology, quantitative microbial risk assessment, microbial physiology, mycotoxicology, and HACCP systems. He also has an ongoing interest in the

development of science-based public health policy; in addition to currently serving as the FDA CFSAN Senior Science Advisor, he also served as Deputy Administrator for Science with the USDA Food Safety & Inspection Service. Dr. Buchanan is a member of the National Advisory Committee on Microbiological Criteria for Foods and the International Commission for Microbiological Specifications for Foods, was a member of the National Academy of Sciences' Institute of Medicine Committee on Emerging Microbial Threats, and is on the editorial boards of several journals. He has published approximately 300 manuscripts, book chapters, and abstracts on a wide range of subjects related to food safety, and is one of the co-developers of the widely used USDA Pathogen Modeling Program.

VICTORIA DURANT-GONZALEZ, Ph.D.

Director of Community Service
Spelman College

Dr. Durant-Gonzalez is the Director of Community Service at Spelman College and is responsible for providing community service opportunities for over 1800 students and service learning opportunities for the faculty. She has developed the Harris Homes First Grade Initiative Partnership and the foundation for the Johnnetta B. Cole Institute for Community Service and Community Building (JBCI). From 1992 - 1996, Dr. Durant-Gonzalez served as the Cluster Coordinator and Cluster Support Facilitator Coordinator for the Atlanta Project, targeting specific community organizations to ensure their support and participation, and securing the award of a 1.2 million-dollar grant from the State of Georgia. She also taught African-American Anthropology, Anthropology of Development, Cross-Cultural Sex Stratification, Community Development and Urban Anthropology, from 1991-1992, as an Assistant Professor at Georgia State University.

In addition, Dr. Durant-Gonzalez has been an active participant in community service, Programs in Public Housing Communities, designing and implementing a family art book program and a photography program for public housing families on behalf of NEXUS Contemporary Art Center. She has also published several articles and reports.

DAVID W. FEIGAL, Jr., M.D., M.P.H.

Director, Center for Devices and Radiological Health
Food and Drug Administration

Dr. Feigal is a native Minnesotan whose education includes a B.S. from the University of Minnesota and M.D. from Stanford University Medical School and a M.P.H. from the University of California Berkeley. He did his Internal Medicine residency training at the University of California at Davis Medical Center and a fellowship in Clinical Epidemiology at the University of California at San Francisco. He joined the UCSF School of Medicine faculty in 1984 with joint appointments in the Departments of Medicine, and Epidemiology and Biostatistics. In 1989 he moved to the Department of Medicine at the University of California, San Diego.

He came to the Food and Drug Administration in 1992 to head the Division of Anti-viral drug products, a position he held until 1997. In 1996 he was also the acting Division Director of the Anti-Infective Drug Division. From 1994 to 1997 he was been the Director of the Office of Drug Evaluation IV. In the Fall of 1997, he moved to the Center for Biologics Research and Evaluation as the Medical Deputy Director. In the Spring of 1999, the Commissioner of the FDA appointed Dr. Feigal as the Director for the Center for Devices and Radiological Health. He has been a member of a number of committees and panels sponsored by the World Health Organization, National Institutes of Health, the Institute of Medicine, and the Centers for Disease Control. He has represented the FDA in the International Conference on Harmonization, the Tripartite Meetings, and at many regulatory meetings.

JESSE L. GOODMAN, M.D., M.P.H.

Acting Deputy Director
Center for Biologics Evaluation and Research
Food and Drug Administration

Dr. Goodman became Acting Deputy Director (Medicine) of the Center for Biologics Evaluation and Research (CBER) in 1999. CBER is the FDA Center responsible for blood and related products, vaccines and cellular and tissue therapies (including gene therapy) and Dr. Goodman plays an active role in medical and public health oversight of activities in all of these areas, including interactions with other agencies and the public. He came to the FDA's Office of the Commissioner in late 1998 from the University of Minnesota where he first joined the Faculty in 1985 and most recently served as Professor of Medicine and as Director of the Division of Infectious Diseases (currently on leave). 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), 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 and numerous publications in the pathogenesis of infectious diseases, in particular tick-borne infections. His laboratory in Minnesota, with support from NIH, isolated the etiologic agent of human granulocytic ehrlichiosis (HGE) and, more recently, has characterized the basic events involved in the infection of leukocytes, including its cellular receptor. He has been an active clinician, clinical investigator, administrator and educator in the academic setting. With support from the Bush Foundation, Dr. Goodman obtained a MPH in Environmental Health at the University of Minnesota and is interested in improving public health through science-based policy and communication. At FDA, he helped originate and co-chaired both the FDA Task Force and the U.S. Government Interagency Task Force on Antimicrobial Resistance.

DAVID R. LINEBACK, PH.D.

Director
Joint Institute for Food Safety and Applied Nutrition
University of Maryland at College Park

Dr. David R. Lineback, Director, Joint Institute for Food Safety and Applied Nutrition (JIFSAN), University of Maryland at College Park is a carbohydrate chemist and food scientist with an extensive academic background. Before going to Maryland, he was Dean, College of Agriculture at the University of Idaho (1993-1998). He has held academic appointments at North Carolina State University, the Pennsylvania State University, Kansas State University, and the University of Nebraska. He was head of the Department of Food Science at North Carolina State University (1980-1993) and at Pennsylvania State University (1976-1980).

Long active in the American Association of Cereal Chemists (AACC) and the Institute of Food Technologists (IFT), Dr. Lineback served as president of the Institute in 1992-93 and chaired a number of its committees and two regional sections. He served as president of the AACC in 1983-84. He has been a voting member of the Food and Drug Administration's Food Advisory Committee 1991-95, 97-; President-elect 1997-98; President 1998-99. He is a member of the Governing Council of the International Union of Food Science and Technology (1999-) and chairs its Scientific Council (1999-). In 1997 he served as chair of the Joint FAO/WHO Expert Consultant on Carbohydrates in Human Nutrition in Rome. He serves as a scientific advisor to the Food, Nutrition, and Safety Committee of the International Life Sciences Institute (ILSI) - North America. Dr. Lineback has served are Food Update (Board of Governors, 1986-94, 1999-), Starch Round Table (Board of Directors, 1983-), Food Processors Institute (Board of Trustees, 1987-93), and Wheat Industry Council (Regional Advisor, 1982-86). The recipient of several awards, Dr. Lineback earned a B.S. degree in chemistry from Purdue University and a Ph.D. (carbohydrate chemistry) from the Ohio State University.

JOHN R. MARZILLI

Deputy Associate Commissioner for Regulatory Affairs
Food and Drug Administration

Mr. Marzilli currently serves as the Deputy Associate Commissioner for Regulatory Affairs having the responsibility of assisting the Associate Commissioner for Regulatory Affairs with the direction and coordination of compliance activities of the FDA.

He was born in Newton, Massachusetts and following graduation from Newton High School, Mr. Marzilli attended Northeastern University where he received his B.S. Degree in Chemistry in 1975.Subsequent to participating in Northeastern University's Co-op as a Chemist in the FDA Boston District Office, he was hired as an Analytical Chemist - a position he held from 1975 to 1986. In 1986, he was promoted to Scientific Coordinator and transferred to the Division of Field Science in FDA Headquarters, Rockville, Maryland. In October 1989, he accepted a position as Consumer Safety Officer with the FDA's Division of Federal-State Relations. In March 1993, Mr. Marzilli was selected to participate in the Executive Potential Program. This 12 month program, which is under the direction of the U.S. Office of Personnel Management, provides training and development experiences to prepare individuals for executive positions in the federal government. In April 1994, he accepted a position as Deputy Director, Division of Field Science. As Deputy, he served as a focal point in all laboratory functions of the FDA field laboratories. In June 1995, Mr. Marzilli was officially appointed as the Director of FDA's Cincinnati District Office having responsibility for all agency activities within the states of Ohio and Kentucky. In August 1997, Mr. Marzilli was appointed to serve as the Director of FDA's New England states of Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont. In January 2000, Mr. Marzilli was appointed to his current position as the Deputy Associate Commissioner for Regulatory Affairs.

TOBIAS MASSA, PH.D., DABT

Executive Director
Global Regulatory Affairs
Eli Lilly and Company

Tobias Massa, Ph.D., DABT is the Executive Director of Global Regulatory Affairs and is responsible for all regulatory aspects of chemistry, manufacturing and controls for all Eli Lilly products, as well as submission coordination, labeling and medical information. He chairs the Corporate Specifications and Regulatory Information Technology Committees and is a member of the Regulatory/ Quality, New Product Launch, Development-Manufacturing Strategy, Clinical Research and Global Product Labeling Committees. He also is a member of the Continuing Legal Education implementation team, and the Global Development Quality Steering Committee.

Dr. Massa was a toxicologist at the Schering Plough Research Institute from 1978 to 1986 and was Associate Director/Group Leader in Toxicology for Pfizer from 1986 to 1990. He rejoined Schering Plough as Associate Director of Regulatory Affairs in 1990 and was most recently Senior Director of Worldwide Regulatory Affairs (Chemistry/Manufacturing/Controls) prior to joining Lilly as Director of Global Regulatory Affairs in 1998. Dr. Massa is currently chair of the Biology and Biotechnology Committee, and member of the FDAMA implementation team of the Pharmaceutical Research and Manufacturers of America. He also is the chair of the Product Quality Research Institute Steering Committee and is a member of the PQRI Board of Directors. A native of New York City, he received his BA (cum laude) in chemistry from SUNY at Buffalo in 1972 where he was elected to Phi Beta Kappa, and earned his doctorate in biomedical sciences from the Mt. Sinai School of Medicine (CUNY) in 1978. He has been a Diplomate of the American Board of Toxicology since 1981.

G. A. (BERT) MITCHELL

Associate Director, Policy and Regulations
Center for Veterinary Medicine
Food and Drug Administration

Dr. G. A. (Bert) Mitchell served as Director, Health Industries Research at Ralston Purina for 18 years and as the Director of the Bureau of Veterinary Drugs in Canada for 6 years before becoming Director of the Office of Surveillance and Compliance at the FDA, Center for Veterinary Medicine (CVM) in 1988. In 1996, he was made Associate Director of Policy and Regulations and in 1999, he became Acting Deputy Director, Center for Veterinary Medicine. Dr. Mitchell received his D.V.M. degree from the Ontario Veterinary College.

He has been recognized through performance awards from industry and government. He is the recipient of many awards including the McGillivary Award for excellence in leadership as an undergraduate; Supergoal Winner for outstanding achievement over a period of 1,000 days; and Boss of the Year. He was the leader of the team that drafted the BSE regulations. He engaged with the industry and general public to produce the BSE regulations.

BERNARD A. SCHWETZ, D.V.M., PH.D.

Acting Deputy Commissioner, and Senior Advisor for Science
Food and Drug Administration

Dr. Schwetz is the Acting Deputy Commissioner of the Food and Drug Administration (FDA) and the Senior Advisor for Science for the agency. He was director of FDA's National Center for Toxicological Research in Jefferson, Arkansas, from 1993 to 1999. A diplomate of the American Board of Toxicology, Dr. Schwetz was acting Director of the Environmental Toxicology Program at the National Institutes of Health's National Institute of Environmental Health Sciences (NIEHS) in Research Triangle Park, NC, before coming to the FDA in 1993. He was also Associate Director of the National Toxicology program there. He had been Chief of the Institute's Systems Toxicity Branch since 1982. Dr. Schwetz currently serves as Adjunct Professor, Department of Pharmacology and Toxicology/Division of Interdisciplinary Toxicology, at the University of Arkansas for Medical Sciences. He was editor, Fundamental and Applied Toxicology from 1986-1992, and serves on the Editorial Advisory Board, Environmental Health Perspectives and Critical Reviews in Toxicology.

Dr. Schwetz is an invited member of the Commonwealth of Canada Health Protection Branch Science Advisory Board, an elected member of the National Academy of Sciences Institute of Medicine, a member of the Society of Toxicology (SOT) and the National Capitol Area Chapter, SOT; the American Veterinary Medical Association; National Society of Phi Zeta, Honor Society of Veterinary Medicine; Teratology Society; Behavioral Teratology Society; and the Reproductive Toxicology Specialty Section of the SOT. He is past president of the Reproductive Toxicology Specialty Section of the SOT and of the North Carolina Chapter and the South Central Chapters of the SOT. In addition to numerous other professional awards during his career, Dr. Schwetz received the U.S. Government's 1998 Meritorious Executive Presidential rank Award.

LINDA A. SUYDAM, D.P.A.
Senior Associate Commissioner
Food and Drug Administration

As Senior Associate Commissioner, Dr. Suydam is responsible for the development and implementation of processes to implement change and develop new regulatory strategies for the Food and Drug Administration (FDA) to efficiently and effectively operate within a global economy. Dr. Suydam advises the Commissioner on all matters concerning strategic management and oversees all activities within the Office of the Commissioner. One of her principal responsibilities was the development of the initial Agency plan required under Section 406(b) of the Food and Drug Administration Modernization Act of 1997.

Prior to rejoining the Agency in July 1998, Dr. Suydam was the Associate Vice President for Planning and Development of the Health Sciences Center (HSC) at the University of New Mexico in Albuquerque. The HSC is the only comprehensive patient care, education, and research health care organization in New Mexico. Dr. Suydam was responsible for strategic and facilities planning, marketing, public relations, development, research coordination, the animal research facility and the HSC Library.

Dr. Suydam's career at the FDA prior to 1995 spanned 17 years of more progressive responsibility beginning in the Bureau of Medical Devices as a program analyst and including six years as the executive officer for the Center for Devices and Radiological Health; two years as the Associate Commissioner for Operations in the Office of the Commissioner and culminating as the Interim Deputy Commissioner for Operations from April 1994 until September 1995. During her FDA career, Dr. Suydam received numerous awards including the Department of Health and Human Services Secretary's Award for Distinguished Service, the Public Health Service Superior Service Award, two individual FDA Awards of Merit and many group awards.

Prior to joining the FDA in 1978, Dr. Suydam held progressively responsible professional positions in the public and private sector as a counseling administrator, social work supervisor and caseworker. Dr. Suydam holds a BA from the College of New Jersey, an MA from George Washington University, an MPA from the University of California (USC), and a Doctorate in Public Administration from USC. She is married to Dr. Gerald L. Barkdoll and resides in Rockville, Maryland.

JANET WOODCOCK, M.D.
Director, Center for Drug Evaluation and Research
Food and Drug Administration

Janet Woodcock, M.D. is the Director, Center for Drug Evaluation and Research. Prior to this, she was Director, Office of Therapeutics Research and Review, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA). Dr. Woodcock is an internist/rheumatologist with research experience in immunology. She joined FDA in 1985. She served as the Director of the Division of Biological Investigational New Drugs in CBER from 1988-1992 and was Acting Deputy Director of the Center in 1991 and 1992. Dr. Woodcock received her M.D. from Northwestern Medical School, and completed further training and held faculty appointments at the Pennsylvania State University and the University of California in San Francisco.

Collaborating with Stakeholders
Registration Form

If you are interested in attending and/or speaking at one of the *FDA Collaborating with Stakeholders* meetings, please fill out the form below.

Title_____ First Name_____ Last Name _____

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Please select the meeting you would like to register for:

- ☐ Stanford University, Stanford, California, March 23, 2000.
- ☐ Duke University, Durham, N.C., April 12, 2000.

Please indicate below whether you will be presenting comments at the meeting or just attending the meeting.

- ☐ I would like to attend the meeting, but not make a presentation.
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  - ☐ Safety Assurance in Clinical Trials
  - ☐ Gene Therapy, Human Cellular and Tissue Based Products
  - ☐ Risk Management
  - ☐ Internet
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Please specify if you need special accommodations:

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Dr.	Jeffrey	Lawson	Duke University Medical Center
Ms.	Meg	Neal	Duke University Medical Center
Dr.	Gary	Archer	Duke University
Dr.	John	Sampson	Duke University
Mr.	Paul	Manley	Johnson & Johnson Consumer Products WW

PREFIX	FIRST NAME	LAST NAME	ORGANIZATION
Mrs.	Beverly	Brockschmidt	North Carolina Association of Healthcare Quality
Ms.	Susan	Thomason	Quintiles Transnational Corporation
Dr.	Larry	Kessler	FDA-CDRH-OSB
Mr.	Lee	Evans	SAS Institute
Ms.	Kay	Obenshain	SAS Institute
Dr.	Ed	Helton	SAS Institute
Dr.	Joseph	Moore	Duke University Medical Center
Dr.	Lois	Hoppstein	Clinical TeleHealth
Miss	Aubrey	Betts	Duke University, Office of Federal Relations
Mr.	Edward (Bruce)	Williams	NC Dept. of Agriculture & Consumer Services
Ms.	Laura	Greiner	American Cancer Society
Dr.	Katheryn	Connor	Duke Univ. Medical Center
Dr.	Ranga	Krishnan	Duke University Medical Center
	Joel	Weiner	Health Canada
Dr.	Charles	Hamner	North Carolina Biotechnology Center
Dr.	Wajeeh	Bajwa	Duke University Medical Center
Dr.	Barry	Mangum	Quintiles, Inc.
Mrs.	Cindy	Holeman	Duke Clinical Research Institute
Dr.	Christine	Jenkins	Pfizer Animal Health
	Angela	Hatton	Clintrials Research Inc.
Dr.	George	Waterhouse	Serentec, Inc.
Ms.	Mary	Musacchia	SAS Institute
	Martis	Davis	Burson-Marsteller
	Jeff	Richardson	Burson-Marsteller
Mr.	David	Bridge	Quintiles Trasnational
	Alan	Castellion	Global Pharma Associates
Dr.	Paula	Rogenes	Glaxo Wellcome
Dr.	Kathryn	Connor	Duke University Medical Center
Dr.	Ranga	Krishnan	Duke University Medical Center
	Joel	Weiner	Health Canada, Health Protection Branch
Dr.	Bryan	Burlingham	NC AgroMedicare Institute
Ms.	Gwen	Morris	CAS of Cary Inc.
Mr.	Joseph	Freddoso	Cisco Systems, Inc. RTP Campus
Dr.	John	Pitts	Encelle, Inc.
MD.	Elise	Olsen	Duke University Faculty
	Lori	Block	Planned Parenthood
Mr.	Gary	Schrempp	Underwriters Laboratories
Dr.	Alan	Proia	Duke University Medical Center
Mr.	Ed	Helton	SAS Institute Inc.
Ms.	Kay	Obershain	SAS Institute Inc.
	Milton	Bush	The M Companies
Ms.	Kaye	Fendt	Private Consultant
Ms.	Julia	Merricks	Glaxo Wellcome Inc.