FACULTY BIOSKETCHES

National Institutes of Health Clinical Center

"Principles of Clinical Pharmacology" Course

August 2008

Darrell R. Abernethy, M.D., Ph.D.

Chief Science Officer
U.S. Pharmacopeia

Darrell R. Abernethy, M.D., Ph.D. is Chief Science Officer at the United States Pharmacopeia. He assumed this position in June, 2007. Dr. Abernethy received his M.D. (AOA) and Ph.D. (Pharmacology) degrees from the University of Kansas School of Medicine in 1976. Further clinical training was in Internal Medicine at Jackson Memorial Hospital/University of Miami through Board Certification in Internal Medicine. He then did post-doctoral fellowship training in Clinical Pharmacology at the Massachusetts General Hospital. Dr. Abernethy joined the faculty at Tufts University School of Medicine as Assistant Professor of Psychiatry and Medicine in 1981. He moved to Baylor College of Medicine in 1983 where he advanced to Associate Professor of Medicine in the Division of Hypertension and Clinical Pharmacology. In 1986 he moved to Brown University School of Medicine as Chief of the Division of Clinical Pharmacology. He was subsequently promoted to Professor of Medicine at Brown. In 1994 Dr. Abernethy became the Francis Cabell Brown Professor and Director of the Division of Clinical Pharmacology at Georgetown University School of Medicine, where he served until 1999. He then moved to become Chief of the Laboratory of Clinical Investigation at the National Institute on Aging and was at this post until June, 2007, at which time he assumed his current post.

Dr. Abernethy has contributed to understanding of mechanisms of peripheral distribution of drugs and drug disposition and effect in obesity. He also has contributed to the knowledge base in pharmacokinetic/pharmacodynamic relationships of cardiovascular drugs in aging and has advanced the concept that the pathophysiology of aging must be considered when interpreting drug effects in the aged patient. Currently Dr. Abernethy is studying the role of genetic polymorphisms of drug effectors that effect responses to cardiovascular drugs.

Editorial activities include membership on the editorial boards of Clinical Pharmacology and Therapeutics, the Journal of Clinical Psychopharmacology, Drugs, as Associate Editor of the Journal of Pharmacology and Experimental Therapeutics, and he served as Editor-in-Chief of Pharmacological Reviews (2001-2006). Organizational and public service have included serving as President of the American Society of Clinical Pharmacology and Therapeutics (1991-1992) and on the Gerontology Committee of the United States Pharmacoepia (1990-2005) that he subsequently chaired (1999-2005). He also served on the USP Medicare Medication Guidelines committee, a group designated by the US Congress to establish the basis for the Medicare Prescription Drug Benefit (2004-2005). In 2005 he was elected President of the USP Convention for the 2005-2010 cycle.

Arthur J. Atkinson, Jr., M.D.

Adjunct Professor of Molecular Biochemistry and Pharmacology, Feinberg School of Medicine, Northwestern University

Dr. Atkinson received his A.B. degree in Chemistry from Harvard College in 1959 and his M.D. from Cornell University Medical College in 1963. Following medical internship and residency at the Massachusetts General Hospital, he was a Clinical Associate in the Laboratory of Clinical Investigation of the National Institute of Allergy and Infectious Diseases (NIAID) at the NIH. He subsequently received postdoctoral training in clinical pharmacology at the University of Cincinnati and was a Visiting Scientist in the Department of Toxicology at the Karolinska Institute before moving to Northwestern University Medical School in 1970 to start the program in Clinical Pharmacology. While at Northwestern, he and his colleagues set up the first U.S. laboratory devoted to general therapeutic drug monitoring, designed and conducted the first clinical investigations to develop the acetylated metabolite of procainamide as a new antiarrhythmic drug, carried out the first pharmacokinetic studies with stable isotope-labeled drugs, and completed basic research that

elucidated the physiologic basis of some multicompartmental models of drug distribution. In 1994, Dr. Atkinson was appointed Corporate Vice President for Clinical Development and Medical Affairs at the Upjohn Company. Following the Upjohn-Pharmacia merger, he joined the Center for Drug Development science at Georgetown University as an Adjunct Professor of Pharmacology. In 1997, he returned to NIH as a Special Expert Consultant in Clinical Pharmacology for NIGMS, and from 1998 until 2005 held the position of Senior Advisor in Clinical Pharmacology to the Director of the NIH Clinical Center. During that time, he established the NIH evening course on *Principles of Clinical Pharmacology* and served as lead editor for the companion text that was written by the course faculty. Dr. Atkinson has been President of the American Board of Clinical Pharmacology, President of the American Society for Clinical Pharmacology and Therapeutics, and is a Master of the American College of Physicians. He currently serves as an Associate Editor of *Clinical Pharmacology and Therapeutics*.

Frank M. Balis, M.D.
Clinical Director, NCI, NIH and Head, Pharmacology and Experimental Therapeutics Section, Pediatric Oncology Branch, National Cancer Institute (NCI), NIH

Dr. Balis' primary research focus is the clinical pharmacology of anticancer drugs and new drug development for childhood cancers. Dr. Balis came to NCI in 1982 as a clinical associate in the Pediatric Oncology Branch. He became a senior investigator in 1988 and has developed an active preclinical and clinical research program focused on the study of the pharmacokinetics of anticancer drugs used to treat childhood cancers with an emphasis on the study of the central nervous system pharmacology of anticancer drugs, and the development of new treatment approaches for childhood cancers through the development of new drugs. Dr. Balis has also played a role in the NCI's Division of Clinical Sciences' clinical research program, as the founder and chair of the Pediatric Protocol Review Committee, and the former chair of both the NCI's Institutional Review Board and Protocol Review and Monitoring Committee. Dr. Balis received his B.S. in Zoology from the University of North Carolina and his M.D. from Vanderbilt University. He completed a pediatric residency at Vanderbilt Children's Hospital followed by four years of fellowship training in Pediatric Hematology/Oncology at the Children's Hospital in Seattle and the Fred Hutchinson Cancer Research Center.

Karim Anton Calis, Pharm.D., M.P.H,
Director, Drug Information Service and Clinical Specialist, Endocrinology and Women's Health, Department of Pharmacy, NIH Clinical Center, NIH

Dr. Calis is a clinical specialist in endocrinology and women's health for the National Institute of Child Health and Human Development (NICHD) and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) at the National Institutes of Health (NIH). He also is the Director of the NIH Drug Information Service. Dr. Calis earned his Bachelor of Science and Doctor of Pharmacy degrees from the University of Maryland School of Pharmacy and received a Master of Public Health degree from The Johns Hopkins University School of Hygiene and Public Health. Prior to joining the NIH in 1989, he held the positions of Clinical Pharmacy Coordinator and Assistant Director for Clinical Services and served as director of a nutritional and metabolic support service. Dr. Calis is a Fellow of the American College of Clinical Pharmacy and a Fellow of the American Society of Health-System Pharmacists. He is board certified in pharmacotherapy and in nutritional support by the Board of Pharmaceutical Specialties.

Dr. Calis is Clinical Professor at the University of Maryland and Shenandoah University, and

Professor at the Medical College of Virginia, Virginia Commonwealth University. He is a clinical investigator in the NIH intramural research program with a primary focus on disorders of the hypothalamic-pituitary-adrenal axis, female reprodu4ctive endocrinology, physiologic sex-steroid replacement in women, and childhood growth and obesity. Dr. Calis is responsible for drug safety monitoring for a number of ongoing NIH studies and is a member of the NICHD Institutional Review Board. He also has served as a member and chair of several data and safety monitoring boards at the NIH.

Dr. Calis completed a 5-year term on the Expert Panel on Nutrition and Electrolytes and another 5-year term as a member of the Expert Committee on Endocrinology of the United States Pharmacopeial Convention. Currently, Dr. Calis serves as Chair of the USP Endocrinology Expert Committee (an elected position) and Vice Chair of the Medicare Model Guidelines Expert Committee. He also is a member of the USP Council of Experts. Dr. Calis received the Hospital Pharmacist of the Year Award in 1989 from the Washington Metropolitan Society of Hospital Pharmacists and later served as president of that organization. He is the recipient of the McKesson and Squibb leadership awards, the ASHP Research and Education Foundation's Pharmacy Practice Research Award, and the Award for Excellence in Clinical Pharmacy Practice from the Association of Military Surgeons of the United States (AMSUS). In July of 2004, Dr. Calis was elected as a Distinguished Practitioner by the National Academies of Practice. In October of 2005, he was selected as the Honored Alumnus by the University of Maryland School of Pharmacy.

Jerry M. Collins, Ph.D.

Associate Director, Developmental Therapeutics Program, Division of Cancer Treatment and Diagnosis, NCI, NIH

Dr. Collins received his Ph.D. in 1976 from the University of Pennsylvania, and completed a postdoctoral fellowship in Clinical Pharmacology at Johns Hopkins University School of Medicine. In 2005 Dr. Collins returned to the NIH to lead the Developmental Therapeutics Program at the NCI. He has authored or co-authored over 170 papers in the field of clinical pharmacology, primarily emphasizing the applications of PK/PD principles in the fields of cancer. Prior to his current position, he spent 17 years at the FDA where his work also included extending these principles with positron emission tomography. Before joining the FDA, Dr. Collins spent a total of 10 years at the NIH, including 5 years as Chief of the Pharmacokinetics Section at the NCI. Dr. Collins retains an association at the FDA for joint NCI-FDA programs.

Charles E. Daniels, Ph.D.

Professor and Associate Dean, and Pharmacist-In-Chief, School of Pharmacy and Pharmaceutical Sciences, University of California at San Diego

Dr. Daniels received his B.S. in Pharmacy from the University of Arizona then completed a Pharmacy Residency at the NIH. He earned his M.S. and Ph.D. degrees from the University of Minnesota as a fellow of the American Foundation for Pharmaceutical Education (AFPE). He served as a member of the faculty at the University of Minnesota College of Pharmacy for 15 years while holding pharmacy management positions at the University Hospital. As a member of the graduate faculty there, he served as the Major Professor or Research Advisor for over two-dozen students who completed the M.S. or Ph.D. He also served as the Director of Graduate Studies in Hospital Pharmacy. He has precepted more than 50 pharmacy residents in training.

Dr. Daniels has been elected to membership as a Fellow of the American Society of Health-Systems Pharmacists. His research interests include pharmacoeconomics, health related quality of life, and

epidemiological evaluation of medication related events. He has published scientific and professional articles and book chapters on those topics.

Dr. Daniels is currently Professor and Associate Dean, and Pharmacist-In-Chief, School of Pharmacy and Pharmaceutical Sciences at the University of California at San Diego.

Before joining UCSD Dr. Daniels was Chief of the Pharmacy Department at the NIH Clinical Center where he was responsible for comprehensive pharmaceutical services, new drug development support programs, and pharmacy-based research programs.

Robert L. Dedrick, M.S.E., Ph.D.
Special Volunteer and former Director, Drug Delivery and Kinetics Resource, Bioengineering and Physical Science Program, NIH

Dr. Dedrick received his formal training in chemical engineering at Yale University (B.E. with highest honors), the University of Michigan (M.S.E.) and the University of Maryland (Ph.D.). Following a few years on the faculty of the George Washington University he was asked to develop a Chemical Engineering Section to provide support to the intramural program of the NIH. Most of the section staff and its portfolio of projects have been reorganized into the Drug Delivery and Kinetics Resource. Resource activities include physiological pharmacokinetics, pharmacokinetics of macromolecules, regional drug administration, spatially distributed models, kinetics, fluid mechanics, and related applications of engineering science and technology to biomedical research. His approximately 170 publications include discussions of the physiologic bases of pharmacokinetics and of numerous applications to pharmacology and toxicology such as *in vitro-in vivo* correlations, interspecies scaling and the design of Phase I clinical trials. He is recipient of the Scientific Achievement Award (Engineering Sciences) of the Washington Academy of Sciences, the Food, Pharmaceutical and Bioengineering Award of the American Institute of Chemical Engineers, the Founders' Award of the Chemical Industry Institute of Toxicology and is a Founding Fellow of the American Institute of Medical and Biological Engineering. His research interests includes microdialysis, the pharmacokinetics of macromolecules, intraperitoneal drug administration, pulmonary delivery of chemoprevention agents, and intra-arterial and intratissue drug infusion with particular emphasis on drug delivery to the brain.

David A. Flockhart, M.D., Ph.D.
Professor of Medicine, Genetics and Pharmacology
Chief, Division of Clinical Pharmacology
Indiana University School of Medicine

In the summer of 2001, Dr. Flockhart came to Indiana University from Georgetown University Medical Center, where he served as the Francis Cabell Brown Chair and Chief of the Division of Clinical Pharmacology and Director of the Pharmacogenetics Core laboratory. His research is focused on clinically-relevant applications of pharmacogenetics and drug interactions. He grew up in Edinburgh, Scotland and took Honors in Biochemistry at the University of Bristol, England. He subsequently obtained a Ph.D. from the Welsh National School of Medicine, and an M.D. from the University of Miami School of Medicine. He was an Internal Medicine resident at Georgetown University Medical Center, and after a year as Chief Medical Resident, completed a fellowship in Clinical Pharmacology in the Division of Clinical Pharmacology at Georgetown. He joined the faculty of the Georgetown Division of Clinical Pharmacology in 1993, and was appointed Director of the Pharmacogenetics Core Laboratory in1995.

Dr. Flockhart has been involved in the development of new pharmacogenetic tests using array, chip and other biotechnologies, and a focus of his research is to evaluate and communicate the value of pharmacogenetic tests to physicians and pharmacists involved in clinical practice. He is now the Principal Investigator of the Indiana University Medical Center site of the national Pharmacogenetics Research Network organized by NIGMS. Dr. Flockhart has more than 100 publications in the area of pharmacology and clinical pharmacology, in which he specializes in the study of drug interactions and the contribution of genetics to inter-individual variations in drug response. He is a member of the American Board of Clinical Pharmacology and has served on the Executive Committee and Board of the American Society for Clinical Pharmacology and Experimental Therapeutics, and as Chair of the Government Affairs Committee. He is currently the Vice-Chair of the Pharmacokinetics and Drug Metabolism Section of ASCPT. Dr. Flockhart is an active teacher, and teaches the Clinical Pharmacogenetics portion of the annual course in Clinical Pharmacology at the National Institutes of Health, in Bethesda, MD and the Pharmacogenetics section of the Annual Review in Clinical Pharmacology provided by the ASCPT. He also provided the "Clinical Pharmacology Update" module at the Annual Meeting of the American College of Physicians in Atlanta, GA in 2001.

Dr. Flockhart's website "drug-interactions.com", a tool to improve rational prescribing, has been cited by the Washington Manual of Medicine and Therapeutics, The Harriet Lane Handbook for Pediatrics and the Medical Letter, and receives approximately 2000 visits per month from physicians and scientists from around the world.

David M. Foster, Ph.D.

Research Professor Emeritus, Department of Bioengineering, College of Engineering and School of Medicine, University of Washington

Dr. Foster received his undergraduate degree in mathematics from Northwestern University and his doctoral degree in mathematics from the University of British Columbia. After postdoctoral fellowships in mathematics at the University of Bristol and in physiology at the University of Michigan School of Medicine, Dr. Foster joined the Laboratory of Theoretical Biology of the National Cancer Institute as a Senior Staff Fellow. In this capacity, he worked from 1976 to 1980 with the late Mones Berman, who developed the SAAM computer program for pharmacokinetic analysis.

After leaving NIH in 1980, Dr. Foster joined the faculty of the Center for Bioengineering in the College of Engineering and School of Medicine at the University of Washington. In 1986, he founded the Resource Facility for Kinetic Analysis in the University's bioengineering department and developed a contemporary version of the SAAM program (SAAM II), and in 1995 became CEO of the SAAM Institute which distributed this program. Dr. Foster is the recipient of numerous honors and has published over 98 papers and textbook chapters on both the theory and application of kinetic modeling techniques.

Marilynn C. Frederiksen, M.D.

Associate Professor of Obstetrics and Gynecology, Department of Obstetrics and Gynecology, Northwestern University Medical School

Dr. Frederiksen received her undergraduate degree from Cornell College in Mount Vernon, Iowa and her M.D. degree from Boston University School of Medicine. She had residency training in pediatrics at the University of Maryland School of Medicine and in obstetrics and gynecology at the Boston Hospital for Women of Harvard University. Following her residency, she had a clinical fellowship in maternal fetal medicine and a research fellowship in clinical pharmacology at Northwestern.
Dr. Frederiksen is board certified in obstetrics and gynecology, maternal fetal medicine, and clinical pharmacology.

From 1989 through 1992 Dr. Frederiksen was a member of the NIH National Center for Research Resources (NCRR) General Clinical Research Center (GCRC) Committee, serving as Chair from 1992 through 1993, and she has served on a number of other NIH study sections and special review committees. Dr. Frederiksen's research work on drugs used for pregnant asthmatics led to her being asked to serve on the 1991-1992 NHLBI Task force on Asthma and Pregnancy. This task force developed guidelines for the care and treatment of pregnant patients with asthma. In 1992, Dr. Frederiksen was invited to speak on Clinical Trials in Pregnancy at an FDA symposium on Women in Clinical Trials and was an invited speaker at two workshops on pharmacokinetics in pregnancy that were held by NICHD and by the FDA.

Pamela D. Garzone, Ph.D.
Principle, PD3G Consulting

Dr. Garzone has extensive product development experience in biotechnology and has held positions of increasing responsibility in a number of US biotechnology companies. Currently she is the Principle in her consulting company, PD3G Consulting. Previously she was Director of Clinical Pharmacology at ChemoCentryx, Inc., a clinical stage biopharmaceutical company focused on discovering and developing orally-administered medicines that target the chemokine system. Dr. Garzone has been responsible for the preclinical and clinical development of proteins, peptides and small molecules, and the execution of those development plans, as well as several successful product license application submissions in the United States and in Europe. Her training and expertise is in the application of pharmacokinetic and pharmacodynamic principles for biologics and drugs in the drug development process. Prior to her industrial experience, Dr. Garzone was on faculty at the University of Pittsburgh School of Pharmacy, doing research in the CNS area and teaching undergraduate and graduate students. She also was a clinical pharmacy practitioner at a teaching hospital in Pittsburgh. Dr. Garzone received a Bachelor of Science in Pharmacy from Purdue University in 1977 and a Master of Science and Doctor of Philosophy degree from the University of Pittsburgh in 1981 and 1987, respectively.

Michael M. Gottesman, M.D.
Deputy Director for Intramural Research, NIH

Dr. Gottesman attended Harvard College where he graduated summa cum laude in biochemical sciences in 1966. He graduated from Harvard Medical School with an M.D. degree magna cum laude in 1970 and completed a medical internship and residency at the Peter Bent Brigham Hospital in Boston. His research training began at Harvard in the laboratories of William Beck and Bert Vallee, and continued in the laboratory of Martin Gellert at the NIH as a Research Associate from 1971 to 1974. Dr. Gottesman spent a year as an Assistant Professor at Harvard Medical School and then, together with his wife who is a bacterial geneticist, joined the permanent staff of the National Cancer Institute (NCI) in 1976. He became Chief of the Molecular Cell Genetics Section of the Laboratory of Molecular Biology in 1980, Chief of the Laboratory of Cell Biology in 1990, Acting Director of the National Center for Human Genome Research (NCHGR) from 1992 to 1993, and also Acting Scientific Director of the NCHGR (April 1993 to October 1993). He became Deputy Director for Intramural Research, NIH in November 1993, and Assistant Surgeon General (Rear Admiral), Public Health Service in 1997.

At the NIH his research interests have ranged from how DNA is replicated in bacteria to how cancer cells elude chemotherapy, and he has published extensively on these subjects. Using chloramphenicol resistance as a model, he was one of the first to show that drug resistance genes could move from one replicon to another in bacteria. Applying the tools of molecular and somatic cell genetics to the study of cAMP-resistance and anti-microtubule drug resistance in mammalian cells, he isolated and characterized cAMP-dependent protein kinase mutants and conditional a- and b-tubulin

mutants. These mutants and novel techniques of DNA transfer, which he was among the first to exploit, were used as tools to demonstrate the role of cAMP-dependent kinase in growth regulation and to study the effect of microtubule defects on mitosis. The work on anti-microtubule drug resistance led to studies on multidrug resistance in human cancer cells. During the past 12 years, in close collaboration with Ira Pastan, he has identified the human gene responsible for resistance of cancer cells to many of the most common anti-cancer drugs and has shown that this gene encodes a protein which acts to pump anti-cancer drugs out of drug-resistant human cancers. In addition to the development of strategies to circumvent multidrug resistance in cancer, these studies have led to a new generation of selectable vectors for gene therapy.

Dr. Gottesman's professional activities include many active memberships in professional societies and editorial boards. He was elected a Fellow of the AAAS in 1988 and received the Milken Family Foundation Cancer Research Award in 1988, the Rosenthal Foundation Award in 1992, and the ASPET Award in 1997. Dr. Gottesman has been actively involved in initiating several training and mentoring programs for high school students and teachers, college, and graduate students. As Deputy Director for Intramural Research at the NIH, he has initiated an NIH-wide lecture series, reformulated tenure and review processes in the intramural program, and he has instituted training programs for minority and disadvantaged students, loan repayment programs for clinical researchers at the NIH, and a clinical research training program for medical students.

Charles Grudzinskas, Ph.D.

Co-Founder and Principal, NDA Partners, LLC and Adjunct Faculty, Center for Drug Development Science (CDDS), University of San Francisco (UCSF), School of Pharmacy

Charles Grudzinskas received his Ph.D. from the University of Minnesota. He is a co-founder and Principal at NDA Partners, LLC. Dr. Grudzinskas consults on the strategy and tactics of drug development, regulatory strategies and project management, working across the full range of emerging and mature companies. He is also an adjunct faculty at CDDS, UCSF School of Pharmacy.

Dr. Grudzinskas' drug development career includes Vice President, Medications Development and Project Management, G.D. Searle and Company and Director, New Product Management at Lederle Laboratories. Prior to joining Searle, Dr. Grudzinskas was the first director of the Medications Development Division of the National Institute on Drug Abuse (NIDA) at the NIH. During his tenure at NIDA, Dr. Grudzinskas established state of the art anti-cocaine and anti-opiate discovery and clinical development programs. By working closely with the FDA review division and the FDA Drug Abuse Advisory Committee, Dr. Grudzinskas' NIDA division was able to achieve an 18-day approval of LAAM, an alternative to methadone. This remarkable partnership with the FDA included the piloting of a "Rolling NDA Process" which has now been incorporated as part of the FDA Modernization Act of 1997 (FDAMA).

As a member of the 1986-89 FDA/PMA Project Management Working Group, Dr. Grudzinskas recommended to the FDA that to ensure higher quality NDAs, CDER should make better use of their Refuse to File authority. More rigorous enforcement of Refuse to File has played a role in ensuring higher quality NDAs, resulting in shortening NDA review times. Dr. Grudzinskas played a major role in the creation of role of Project Managers within CDER prior to PDUFA. Dr. Grudzinskas has been the course director for the PERI Drug Development Course and is a faculty member of PERI Courses in Project Management, R&D Finance, Clinical Trials, Primer for New Physicians and Scientists, and the NDA Game. Dr. Grudzinskas is a registered U.S. Patent Agent.

Robert B. Innis, M.D., Ph.D.
Chief, Molecular Imaging Branch, National Institute of Mental Health, NIH

Dr. Innis received his B.S. degree from Yale University in 1974 and an M.D. from Johns Hopkins in 1978. He obtained a Ph.D. degree in neuropharmacology from Johns Hopkins in 1981 under the mentorship of Solomon Snyder. After completing a residency in psychiatry at Yale University in 1984, he joined their faculty in the Departments of Psychiatry and Pharmacology. Dr. Innis left Yale in 2001 to become Chief of a new laboratory at NIMH with an emphasis on brain imaging using PET (positron emission tomography). Expanded state-of-the-art facilities for both radiochemistry and PET imaging at NIH provide unique opportunities for the application of this radiotracer method to patients with neuropsychiatric disorders. The overall goals of Dr. Innis' laboratory are to develop new radiotracers that image molecular targets in the brain, to evaluate these tracers in animals and healthy human subjects, and then to extend their use to patients with neuropsychiatric disorders.

See the following web site for additional information on Dr. Innis' laboratory, including recent findings, representative publications in pdf format, and current studies
http://intramural.nimh.nih.gov/mood/proginfo/mib/neuro.htm.

Juan J. L. Lertora, M.D., Ph.D.
Director, Clinical Pharmacology Program, NIH Clinical Center, NIH

Dr. Lertora joined the NIH in July of 2006 as Director, Clinical Pharmacology Program, Division of Clinical Research Training and Medical Education, and works at the NIH Clinical Center in Bethesda, Maryland. Before joining the NIH, he was Professor of Medicine and Pharmacology and Section Head of Clinical Pharmacology (1981-2006) at Tulane University School of Medicine in New Orleans, Louisiana. During 1998-2005 he was Program Director for the Tulane-Louisiana State University-Charity Hospital General Clinical Research Center (GCRC) sponsored by the National Center for Research Resources at the NIH. Dr. Lertora served as Vice Chair and Chair of the Institutional Review Board at Tulane (1982-1996) and was the Principal Investigator of the NIAID-funded Tulane-LSU Adult AIDS Clinical Trials Unit (1996-2005). In addition Dr. Lertora served as Core Faculty for the K30 Mentored Clinical Research Curriculum Award, also funded by NIH (2001-2006). Currently Dr. Lertora is Adjunct Professor of Medicine at Duke University School of Medicine.

Dr. Lertora's research interests include phase I-II safety and efficacy clinical trials, pharmacokinetics, drug metabolism, pharmacogenetics, drug interactions, and pharmacodynamics of novel therapies for HIV/AIDS and resistant *M. tuberculosis*. Previously, he also conducted research on erythropoietin's role in the anemia of chronic renal disease, dose-related cardioselectivity of practolol, N-acetylprocainamide (NAPA) antiarrhythmic and inotropic actions, cardiovascular actions and pharmacokinetics of desethyl-N-acetylprocainamide (NAPADE), CYP2E1 and chlorzoxazone metabolism, and ribavirin pharmacokinetics in adults and children infected with HIV.

Dr. Lertora is a graduate of the Faculty of Medicine, National University of the Northeast, Corrientes, Argentina, and the Graduate School, Department of Pharmacology, at Tulane University. Some highlights of his career include the Merck Sharp and Dohme International Fellowship in Clinical Pharmacology, training in Internal Medicine at the University of Connecticut and a fellowship in Clinical Pharmacology at the University of Iowa. He was Assistant Professor of Medicine and Pharmacology at the Clinical Pharmacology Center of Northwestern University in Chicago (1977-1981) and was the recipient of a Faculty Development Award from the Pharmaceutical Manufacturers Association Foundation. Dr. Lertora was a member of the Pharmacology Committee for the Adult AIDS Clinical Trials Group (NIAID) during 1987-1993 and 2002-2005. He served on the NIH AIDS Clinical Trials and Epidemiology Study Section (2001-2005), and is a member of the Editorial Board for *Clinical Pharmacology and Therapeutics.* Dr. Lertora is also a member of the FDA Advisory

Committee for Pharmaceutical Sciences and Clinical Pharmacology, and the Board of Directors of the American Society for Clinical Pharmacology and Therapeutics (2007-2011).

Sanford P. Markey, Ph.D
Chief of the Laboratory of Neurotoxicology, National Institute of Mental Health (NIMH), NIH

Dr. Markey received his Ph.D. degree in chemistry from M.I.T., then joined the Departments of Pediatrics and Pharmacology at the University of Colorado. In 1974, Dr. Markey came to the Laboratory of Clinical Science in the NIMH, NIH. Since 1996, Dr. Markey has been Chief of the NIMH Laboratory of Neurotoxicology.

Dr. Markey has authored over 160 scientific papers and two books and has received numerous awards. He has been an Associate Editor of *Organic Mass Spectrometry* and has served on the Editorial Advisory Boards of *Biological Mass Spectrometry* and the *Journal of the American Society for Mass Spectrometry*.

Raymond Miller, D.Sc.
Director of Pharmacometrics, Pfizer, Inc.

Dr. Miller received his B.Sc. degree in Pharmacy in 1968, his M.Sc. (Pharmacology) in 1971 and his D.Sc. (Pharmacology) in 1974 from Potchefstroom University, South Africa. During that time he served as a research scientist for the Medical Research Council. He received postdoctoral training in clinical pharmacology at the University of California, School of Medicine, San Francisco from 1977 to 1979. In 1984 he was appointed Professor and Chairman of the Department of Pharmacology, University of Durban-Westville (UDW), Durban, South Africa. Dr. Miller implemented therapeutic drug monitoring clinics in Durban and extended the discipline nationally. In 1987 he established the Drug Studies Unit at UDW in the Department of Pharmacology and served as the Director. The unit provided research support for the University and implemented pharmacokinetic/pharmacodynamic (PK/PD) techniques in data analysis. During that time Dr. Miller carried out annual workshops on PK/PD modeling to extend the science nationally. Nonlinear mixed effect modeling was implemented by him at UDW and subsequently introduced at key academic institutions throughout the country. In 1994 he joined the Food and Drug Administration as a Senior Staff Fellow in the Division of Pharmacometrics. He implemented novel PK/PD modeling approaches in the agency and applied modeling approaches to answer key regulatory questions. He served as Acting Director of Pharmacometrics at the FDA from 1997-1999. Currently he is Director of Pharmacometrics at Pfizer, Inc.

Diane Mould, Ph.D.
President, Projections Research, Inc.

Dr. Mould received a Ph.D. in Pharmaceutics and Pharmaceutical Chemistry from the Ohio State University College of Pharmacy then held the position of Associate Director in the Department of Drug Metabolism and Pharmacokinetics at Smith-Kline Beecham. During that time, she specialized in population modeling and conducted population PK/PD analyses of hematopoietic, anti-cancer and anti-viral agents, and sedative/hypnotic drugs.

From 2000 until 2002, Dr. Mould was a member of the Georgetown faculty and was involved in clinical trial simulation and the design of drug development studies. Dr. Mould has made numerous national and international presentations of advanced modeling and simulation work and, in addition to serving

as president of her own consulting company, she is a member of the Scientific Advisory Board of the Pharsight company, where she consults on the development of their trial simulation package,

Carl C. Peck, M.D.

Chairman and Founder, NDA Partners LLC
Adjunct Professor, University of California, San Francisco, Center for Drug Development Science/UCSF
University of California-Washington, Washington, DC

Dr. Peck obtained a B.A. in mathematics and chemistry from the University of Kansas in 1963 and the M.D. in 1968. Following training in internal medicine, he undertook a research fellowship in clinical pharmacology at the University of California San Francisco (1972-74). From 1974 to 1980, Dr. Peck was employed at the Letterman Army Institute of Research, San Francisco, CA, as Chief of the Army Blood Preservation Research Program. In 1980, Dr. Peck became Director of the Division of Clinical Pharmacology and, Professor, Departments of Medicine and Pharmacology, Uniformed Services University, Bethesda, Maryland. Dr. Peck joined the FDA as Director, Center for Drug Evaluation and Research, in October 1987. He was promoted to Assistant Surgeon General in the Public Health Service in October 1990. Retiring from FDA in late 1993, Dr. Peck was appointed “Boerhaave” Professor of Clinical Drug Research at Leiden University in The Netherlands. In 1994 Professor Peck joined the faculty of the Georgetown University Medical Center, as the founding Director of the Center for Drug Development Science. In 1999, Dr. Peck received the FDA Distinguished Alumnus Award. Sweden’s University of Uppsala conferred an honorary doctorate degree (Doctor Honoris Causa) to Dr. Peck in January 2002 in recognition of "outstanding contributions to the science of drug development". Dr. Peck founded NDA Partners LLC in 2003 and in 2004, CDDS moved to UCSF, located in the UC-Washington Center. His research interests center on optimizing informativeness, efficiency, speed and economy of drug development and regulation using advanced concepts and techniques of clinical pharmacology, trial designs, and pharmaco-statistical modeling and simulation to generate causal evidence of effectiveness and safety. He is an author of more than 100 original research papers, chapters and books.

Scott Penzak, Pharm.D.

Pharmacokineticist, Clinical Pharmacokinetics Research Laboratory, NIH Clinical Center, NIH

Dr. Penzak received his B.S. in Pharmacy from Ferris State University and his Pharm.D. from Wayne State University. He then completed a two-year fellowship in Infectious Diseases Pharmacology at the University of Arkansas for Medical Sciences. Prior to joining the NIH in September 2001, Dr. Penzak held an Assistant Professor appointment at Mercer University. His areas of research interest include drug metabolism and transport of antiretroviral medications with emphasis on drug-drug interactions and pharmacogenomics.

Lance R. Pohl, Pharm.D, Ph.D.

Chief, Section of Molecular and Cellular Toxicology, Laboratory of Molecular Immunology, National Heart, Lung, and Blood Institute (NHLBI), NIH

Dr. Pohl received both his Pharm.D. and Ph.D. in Medicinal Chemistry from the University of California Medical Center, San Francisco (UCSF). He joined the Laboratory of Chemical Pharmacology NHLBI at NIH as a Postdoctoral Fellow. He has progressed through the ranks at NIH

and is presently Chief of the Section on Molecular and Cellular Toxicology of the Laboratory of Molecular Immunology of the NHLBI.

Dr. Pohl's primary research interests are in the study of the molecular and cellular basis of toxicities caused by reactive metabolites of endogenous molecules and drugs, and he has published over 120 papers, most of which are focused on this area. Dr. Pohl has received numerous awards and honors and is currently an Editorial Board Member for both *Drug Metabolism and Disposition* and *Drug Metabolism Reviews.*

Edward A. Sausville, M.D., Ph.D.

Professor of Medicine, Associate Director for Clinical Research, University of Maryland Greenbaum Cancer Center, University of Maryland in Baltimore

Dr. Sausville received his M.D. and Pharmacology Ph.D. from the Albert Einstein College of Medicine. After training in Internal Medicine at the Brigham & Women's Hospital, he joined the clinical staff of the NCI in 1982 as a Fellow, then rose over the course of several years to the rank of Senior Investigator. From 1988 to 1990, Dr. Sausville served as Associate Professor of Medicine at the Georgetown University School of Medicine but then rejoined the NCI in 1990 and worked in the area of new drug development. The program that Dr. Sausville directed at NCI is charged with the preclinical evaluation of agents potentially suitable for entry into clinical trial for cancer. That included initial demonstration of antiproliferative activity *in vitro*, validation of activity in preclinical *in vivo* models, selection of compounds for further development, and formulation and toxicology experiments to support the preparation of an Investigational New Drug Application (IND). In addition, since 1988 this program has also had an extensive effort to determine novel agents for the treatment of AIDS and AIDS-related malignancies.

In 2004 Dr. Sausville left NIH and is currently Professor of Medicine and Associate Director for Clinical Research at the University of Maryland Greenbaum Cancer Center in Baltimore.

Gregory M. Susla, Pharm.D.

Associate Director, Medical Information MedImmune, Inc.

Dr. Susla received his B.S. in Pharmacy from the University of Connecticut School of Pharmacy in Storrs, Connecticut and his Doctor of Pharmacy degree from the University of Florida College of Pharmacy in Gainesville, Florida. Dr. Susla completed a Specialty Residency in Critical Care Pharmacy at the Ohio State University Hospitals and Clinics in Columbus, Ohio. He is currently Associate Director, Medical Information at MedImmune, Inc. Before joining MedImmune, Inc. Dr. Susla was a Pharmacy Manager with VHA Consulting Services, VHA, Inc. Previously, Dr. Susla was a Clinical Pharmacy Specialist, Critical Care Medicine, and Program Director, Pharmacy Practice Residency Program, Pharmacy Department, NIH Clinical Center, NIH.

Dr. Susla also is a Consultant to the Critical Care Medicine Department, National Naval Medical Center. He is the past Chairman of the Clinical Pharmacology and Pharmacy Section of the Society of Critical Care Medicine, is a Fellow in the American College of Critical Care Medicine and President of the Washington D.C. Area Critical Care Society. Dr. Susla received the 1996 United States Public Health Service Clinical Pharmacist of the year Award. Dr. Susla is a co-author of the Handbook of Critical Care Drug Therapy.

Chris H. Takimoto, M.D., Ph.D.
Senior Director, Translational Medicine
Centocor R&D, Inc./J&J

Dr. Takimoto earned his M.D. at Yale University School of Medicine in New Haven, Connecticut and his Ph.D. in pharmacology from the Yale University Graduate School, both in 1986. He completed his internship and residency in internal medicine at the University of California in San Francisco. Dr. Takimoto completed fellowships in medical oncology at the NCI and in clinical pharmacology at the Uniformed Services University of the Health Sciences in Bethesda, Maryland. Until the spring of 1999, Dr. Takimoto was Senior Investigator, Developmental Therapeutics Department, Medicine Branch, Division of Clinical Sciences, NCI, NIH and Assistant Professor of Medicine, Division of Clinical Pharmacology, Uniformed Services University of the Health Sciences.

Dr. Takimoto is a fellow of the American College of Physicians and a member of the American Association for Cancer Research, the American Society for Clinical Pharmacology and Therapeutics and the American Society for Clinical Pharmacology and Therapeutics and the American Society of Clinical Oncology. He is also an Associate Editor of *Clinical Cancer Research*. His research interests include the pharmacology of novel new anticancer agents, chemotherapy for advanced gastrointestinal tumors and Phase I drug development.

Dr. Takimoto recently joined Centocor R&D, Inc./J&J where he is Senior Director of Translational Medicine. Prior to joining that company he was Director of Pharmacology and Zachry Chair of Translational Research, Institute for Drug Development, Cancer Therapy and Research Center, and Clinical Associate Professor of Medicine, Division of Medical Oncology, University of Texas Health science Center at San Antonio.

Paolo Vicini, Ph.D.,(Bioengineering), LE (Electrical Engineering)
Associate Professor, Department of Bioengineering
University of Washington

Paolo Vicini received his Laurea degree (Electronics Engineering) from the University of Padova, Italy, in 1992, and his Ph.D. (Bioengineering) from the Polytechnic of Milan, Italy, in 1996. His primary appointment is currently as Associate Professor of Bioengineering at the University of Washington, and he holds adjunct appointments in the departments of Pharmaceutics and Oral Biology. He was awarded the Distinguished Teacher-Mentor Award by the Department of Bioengineering in 2006. His research interests include the development of mathematical and statistical methods for modeling biomedical data, with emphasis on software development, design of experiments, statistical model selection and techniques for parameter estimation from data. His research activity at the University of Washington has involved both the development of data analysis software (through the Resource Facility for Population Kinetics, a NIH/NIBIB research resource) and the application of advanced modeling methods to outstanding problems in clinical and basic science, involving glucose and insulin metabolism, pharmacokinetics and pharmacodynamics and model-based image analysis. Examples of software development related to Dr. Vicini's research efforts include the SAAM II system, a widely used simulation and modeling tool (http://depts.washington.edu/saam2), currently licensed by the University of Washington, and the System for Population Kinetics (http://www.rfpk.washington.edu) web service. Both systems have hundreds of registered users worldwide. Dr. Vicini is a member of the American Diabetes Association, the Biomedical Engineering Society, the American Association of Pharmaceutical Scientists, the American Society for Clinical Pharmacology and Therapeutics and the IEEE and Engineering in Medicine and Biology Society. He was the Chair-Elect, Chair and Past Chair of the AAPS Modeling and Simulation Focus Group (1999-2005) and received the IEEE/EMBS Early

Career Award in 2003. He has been a charter member of the Biomedical Computing and Health Informatics NIH Study Section since 2005, and is a member of the Editorial Board of the Journal of Pharmacokinetics and Pharmacodynamics.

Joseph Ware, Ph.D.

Senior Scientist
Clinical Pharmacokinetics & Pharmacodynamics (PK/PD)
Section of Developmental Sciences, Genentech, Inc.

Dr. Ware obtained his Ph.D. from Wayne State University, in the Department of Pharmaceutical Sciences in 1996 from Dr. Craig Svensson. Between 1996 and 1999 he completed a postdoctoral fellowship under the mentorship of Dr. Lance R. Pohl in the Molecular Toxicology Section, Laboratory of Molecular Immunology, NHLBI, NIH. While at the NHLBI, he also studied renal transporters with Dr. Mark Knepper in the LKEM. In 1999, Dr. Ware joined the Pharmacia and Upjohn Company in Kalamazoo, Michigan. While at Pharmacia he initiated a cross-functional transporter biology platform with connectivity to drug discovery, preclinical development, and clinical pharmacology (mouse to man). In September of 2003, Dr. Ware transferred to Pfizer Ann Arbor where he had the opportunity to incorporate genetically modified mice into the preclinical ADMET setting. During his industrial tenure, Dr. Ware mentored numerous graduate and undergraduate students and has served as an adjunct professor at the University of Kansas and the University of West Virginia.

Dr. Ware is currently a Senior Scientist in the Clinical Pharmacokinetics & Pharmacodynamics (PK/PD) Section of Development Sciences at Genentech, Inc., South San Francisco, California. His primary responsibilities include elucidation of a comprehensive clinical pharmacology strategy for oncology “small Molecule” drug candidates which are currently under investigation at Genentech, Inc. He also participates in an international transport working group that includes many pharmaceutical scientists from universities, the FDA, and industry.

Janet Woodcock, M.D.

Director, Center for Drug Evaluation and Research, Food and Drug Administration (FDA)

Dr. Woodcock is Director of the Center for Drug Evaluation and Research (CDER) at the FDA. She 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.

Dr. Woodcock joined FDA in 1986 and is currently responsible for overseeing cross-cutting regulatory and scientific processes at CDER. She has played a key role in the FDA Critical Path initiative over the past several years. Dr. Woodcock also served in other positions at FDA including Director, Office of Therapeutics Research and Review, Acting Deputy Director, Center for Biologics Evaluation and Research, and Chief Medical Officer for the FDA.