March 1, 2006

Invitation for Comments on the "Short List" Candidates for the EPA Human Studies Review Board

EPA Office of the Science Advisor

On January 3, 2006, the EPA, Office of the Science Advisor (OSA) announced a request for nominations of qualified individuals to serve on the EPA Human Studies Review Board (HSRB) (*Federal Register* 71 116). Information on the HSRB, including the nomination process, appears in the above-referenced *Federal Register* notice and on the HSRB Web site at: http://www.epa.gov/osa/hsrb/ As stated in the *Federal Register* notice, the OSA requested nominees who are nationally-recognized experts in one or more of the following disciplines:

(a) Biostatistics. Expertise in statistical design and analysis of human subjects research studies.

(b) Human toxicology. Expertise in pharmacokinetic and toxicokinetic studies, clinical trials, and toxicology of cholinesterase inhibitors and other classes of environmental substances.

(c) Bioethics. Expertise in the ethics of research on human subjects; research ethics.

(d) Human health risk assessment.

The OSA has reviewed the nominations and identified 20 candidates to serve on the HSRB. Brief biographical sketches ("biosketches") on these candidates are provided below. The OSA hereby invites comments from members of the public for relevant information or other documentation that the OSA should consider in the selection of HSRB members.

Any information furnished by the public in response to this Web site posting will be combined with information already provided by the candidates, and gathered independently by the OSA. Prior to final selection of HSRB members, the combined information will be reviewed and evaluated for any possible financial conflict of interest or a possible appearance of a lack of impartiality. The information will also be used to ensure appropriate balance and breadth of expertise needed to address the charge to the Board. The EPA Science Advisor will make the final decision concerning who will serve on the HSRB.

Please e-mail your comments no later than no later than noon, eastern time, March 14, 2006 to Paul Lewis, OSA, at: lewis.paul@epa.gov

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HSRB CANDIDATE BIOSKETCHES

Dr. David Bellinger

Dr. David C. Bellinger is Professor of Neurology, Harvard Medical School, Professor in the Department of Environmental Health, Harvard School of Public Health (HSPH), and Senior Research Associate in Neurology and Psychiatry, Children's Hospital Boston. He received a Ph.D. in Psychology from Cornell University in 1977 and completed post-doctoral fellowship training at the University of Rochester School of Medicine and Boston University. In 1987, he received a M.Sc. in Epidemiology from the HSPH. He received a Research Career Development Award from the NIEHS (1985-1990). He currently directs an NIH-funded T32 Interdisciplinary Training Program in Neurodevelopmental Toxicology at the HSPH. He has served on several committees of the National Academies/National Research Council/ Institute of Medicine, including Measuring Lead Exposure in Infants, Children, and Other Sensitive Populations; Toxicological Effects of Methylmercury; Submarine Escape Action Levels; and Nutrient Relationships in Seafood: Balancing the Benefits and Risks. He has participated in World Health Organization (WHO) consultations involving lead, mercury, and principles of risk assessment. On several occasions, he has been a Technical Advisor to the FAO/WHO Joint Expert Committee on Food Additives and Contaminants (JECFA), as well as serving as a member of JECFA. From 2001-2004, he was a member of the Federal Advisory Committee of the National Children's Study. He participated in the EPA Science Advisory Board review of the Agency's Mercury Report to Congress. He has served as Epidemiology Section Editor of Neurotoxicology and Teratology and is the editor of a forthcoming volume on *Human Developmental Neurotoxicology*. His major research interests are the developmental impact of early metabolic and chemical insults to the nervous system and neuropsychological toxicology. Much of his research has focused on the neurotoxicity of metals in children, particularly lead, mercury, arsenic, and manganese. His research has been funded primarily by the NIH (NICHD, NIEHS, NINDS, NIDCR, NHLBI), and by EPA, the Agency for Toxic Substances and Disease Registry, and Harvard University.

Dr. Stephen Brimijoin

Dr. Stephen Brimijoin is Clement Professor and past Chair (1993-2003) of Pharmacology at Mayo Medical School and Distinguished Investigator at Mayo Clinic, which he joined in 1971 after two years at the National Institutes of Health. For over thirty years he has investigated the neurobiology, pharmacology, and toxicology of cholinesterase enzymes, including studies on the pathophysiology of their axonal transport in human peripheral nerve. He contributed substantially to knowledge of the cellular distribution and fate of the molecular forms of these enzymes in brain. He discovered that anti-esterase antibodies destroy central sympathetic neurons in a selective manner that provides insights into the pathophysiology of the autonomic nervous system. He used genetically engineered neuronal cell lines to show that this acetylcholinesterase may promote nerve growth and maturation, in addition to regulating cholinergic transmission. More recently, his research team modified human plasma cholinesterase to produce a cocaine-metabolizing enzyme that blocks physiological responses to this drug and may pave the way for a gene therapy of addiction. In cholinergic toxicology, Dr. Brimijoin helped generate more potent oxime reactivators to rescue individuals from pesticide

overdose, and he devised a new method to detect cholinesterase inhibition that yields more precise benchmark doses for carbamate pesticides. He is now investigating the developmental neurotoxicity of organophosphates, on which he provided invited testimony to the NAS Committee on the Use of Third Party Toxicity Research with Human Research Participants. Dr. Brimijoin has served on the editorial boards of several journals (currently, Molecular and Cellular Neurobiology) and on the Mayo Human Studies Committee (IRB). For over ten years he has been an ad hoc member of multiple sessions of the EPA FIFRA Scientific Advisory Panel (FIFRA SAP). In recognition for research accomplishments, he received a Javits Neuroscience Investigator Award (1987-94) a Humboldt Foundation Senior Distinguished U.S. Scientist Award (1987-88) and an annual Distinguished Investigator Award from Mayo Clinic (1992-present). He completed his undergraduate and graduate training at Harvard (B.A., 1964; Ph.D., 1969).

Dr. Alicia Carriquiry

Dr. Alicia Carriquiry is professor of statistics and director of graduate education at Iowa State University. Between January of 2000 and July of 2004 she was Associate Provost at Iowa State University. Her research interests are in Bayesian statistics and general methods. Her recent work focuses on nutrition and dietary assessment, as well as on problems in genomics, forensic sciences and traffic safety. She currently teaches the graduate-level course on Bayesian data analysis at Iowa State University and has five doctoral students working under her supervision at this time. She is an elected member of the International Statistical Institute and a Fellow of the American Statistical Association. Dr. Carriquiry served on the Executive Committee of the Institute of Mathematical Statistics between 1999 and 2005 and has been a member of the Board of Trustees of the National Institute of Statistical Sciences since 1997. She is also a past president of the International Society for Bayesian Analysis (ISBA) and a past member of the Board of the Plant Sciences Institute at Iowa State University. Dr. Carriquiry is Editor of *Statistical Sciences* and of *Bayesian Analysis*, Associate Editor of *Statistical Surveys* and serves on the editorial boards of several Latin American journals of statistics and mathematics. She has served on three National Academy of Sciences committees: the Subcommittee on Interpretation and Uses of Dietary Reference Intakes; the Committee on Evaluation of USDA's Methodology for Estimating Eligibility and Participation for the WIC Program and the Committee on Third Party Toxicity Research with Human Research Participants. Currently, she is a member of the standing Committee on Applied and Theoretical Statistics of the National Research Council, the Committee on Assessing the Feasibility, Accuracy and Technical Capability of a Ballistics National Database of the National Research Council and of the Committee on Gender Differences in the Careers in Science, Mathematics and Engineering Faculty of the National Academy of Sciences. She is a member of the Federal Steering Committee Future Directions for the CSFII/NHANES Diet/Nutrition Survey: What we Eat in America and also a member of the NIH Kidney, Nutrition, Obesity and Diabetes Study Section. Carriquiry received a MSc in animal science from the University of Illinois, and an MSc in statistics and a PhD in statistics and animal genetics from Iowa State University.

Dr. Janice Chambers

Dr. Chambers is the William L. Giles Distinguished Professor and Director, Center for Environmental Health Sciences Professor, Department of Basic Sciences at Mississippi State University. Dr. Chambers directs several research projects that deal with the effects of pesticides in mammalian systems to determine the potential human health effects of pesticide exposures. Specifically, there are projects related to the neurochemical and behavioral effects of pesticides in developing organisms as well as the metabolism of pesticides in developing organisms to yield predictions about potential effects of pesticides in infants and children. Other projects are involved in developing mathematical predictions of the effects of mixtures of pesticides on the nervous system so that predictive models can be generated to potentially describe the effects of future uncharacterized mixtures. Dr. Chambers has been the Principal Investigator for numerous federally funded competitive grants in the field of toxicology. Because of her expertise, she has been asked to serve on a number of advisory boards and prestigious committees. Dr. Chambers is board certified as a toxicologist by the American Board of Toxicology and the Academy of Toxicological Sciences. As Director of the Center for Environmental Health Sciences, she has developed an interdisciplinary research center specializing in pesticide toxicology and funded primarily by NIH. The center comprises the areas of neurotoxicology, biochemical toxicology, analytical chemistry, biostatistics, epidemiology, computational chemistry, computational simulation, biochemistry, and endocrinology. Dr. Chamber is a member of the EPA FIFRA Scientific Advisory Panel.

Dr. Gary Chadwick

Dr. Gary Chadwick is the Associate Provost and Director of the Office for Human Subject Protection at the University of Rochester (UR). Dr. Chadwick holds faculty appointments in the School of Medicine and Dentistry (SMD) as Clinical Professor of Community and Preventive Health (Health Policy and Ethics) and Clinical Professor of Medical Humanities (Research Ethics). Since arriving at the University, Dr. Chadwick has been active in teaching research ethics to graduate and medical students, serving on institutional committees for Ethics (Clinical), Conflict of Interest (both for SMD as well University-wide), and Compliance (UR). Dr. Chadwick's former research interests were in suicidology, alcoholism, drug abuse and health services administration, however, his current research activity is serving as an ethics consultant (unpaid) on some federal grants.

Before joining the University of Rochester, Dr. Chadwick was a commissioned officer in the U.S. Public Health Service for over 26 years. He served in the Food and Drug Administration (FDA) where he was the Associate Director for Human Subject Protection in the Office of the Commissioner and was a Senior Scientific Reviewer in the Division of Scientific Investigations of the FDA's Center for Drug Evaluation and Research. Dr. Chadwick has also worked in the Office for Protection from Research Risks at the National Institutes of Health. He is a Past President of Applied Research Ethics National Association (ARENA). He was the founding Chair of the ARENA Council for Certification of IRB Professionals. He is the co-author of the widely used investigator training book, "Protecting Study Volunteers in Research." Dr. Chadwick is a subcommittee member (Subpart A) of the DHHS Secretary's Advisory Committee for Human Research Protection. He earned his BS in Pharmacy from the Ohio State University,

his PharmD from the University of Tennessee, and his MPH from the Uniformed Services University.

Dr. James Chen

Dr. James Chen is Senior Biomedical Research Service – Senior Mathematical Statistician- in the Division of Biometry and Risk Assessment at the National Center for Toxicological Research, U.S. Food and Drug Administration. He is also an Adjunct Professor in the Department of Biostatistics, University of Arkansas for Medical Sciences. He received his B.S. degree from Taiwan Tsing-Hua University, M.A. degree from the University of Pittsburgh, and his Ph.D. from Iowa State University. Dr. Chen is an elected Fellow of the American Statistical Association. He has over 100 scientific publications in peer-reviewed journals and numerous invited subject review articles. Dr. Chen has served on the FDA, EPA, and interagency committees and workshops that directed at developing scientific and regulatory issues and guidelines, and has provided consultations to FDA and EPA scientists on the statistical analysis of toxicological data and risk assessment procedures. Dr. Chen is an associate editor of Communication in Statistics, and the Journal of Biopharmaceutical Statistics.

Dr. George Corcoran

Dr. Corcoran is Professor and Chairman of the Department Pharmaceutical Sciences, College of Pharmacy & Health Sciences, Wayne State University, and Adjunct Professor of Pediatrics, Wayne State University School of Medicine. He earned his B.A. in Chemistry (Ithaca College - 1970), M.S. in Chemistry (Bucknell University - 1973), and Ph.D. in Pharmacology and Toxicology (George Washington University -1980), before completing Post-Doctoral training in Toxicology (Baylor College of Medicine, The Methodist Hospital - 1981). Prior to his Wayne State appointment, Dr. Corcoran served as Assistant Professor of Pharmaceutics at the State University of New York at Buffalo, followed by 9 years at the University of New Mexico in Albuquerque, NM as Associate Professor and later Professor, and Director of the Toxicology Graduate Program.

Dr. Corcoran has published over 170 original research papers, abstracts and other reports, and has received nearly $4 million in grants and contracts as Principle Investigator, Co-Principal Investigator, and Co-Investigator. He has chaired grant review panels for NIH, the National Academies, and the Howard Hughes Medical Institute, and has reviewed papers for more than 50 national and international scientific journals. He has contributed to the training of over 150 MS and PhD graduates, 2500 pharmacists, and many hundreds of undergraduate students.

At the University of New Mexico, he served under Vice President for Health Sciences Jane Henney (FDA Director 1998-2000) as a member of her Health Sciences Leadership Council. He is now Vice-President Elect of the Society of Toxicology, a 5500-member organization of academic, industry and government scientists practicing in the USA and 45 foreign countries. He will become Vice President in 2006-2007, and President in 2007-2008. He has contributed to Society positions having national and international impact, ranging from the best science for rational safety legislation, to organizational ethics and governance.

Dr. Joseph DeGeorge

Dr. Joseph DeGeorge received his Ph.D. in Pharmacology at the New York State Medical Center, Syracuse, NY in 1980 investigating the role of cell surface glucocongugates in axonal regeneration. Dr. DeGeorge was a Postdoctoral Fellow at the University of North Carolina, Chapel Hill, in the Department of Childrens Health (1980-83) investigating glial transmembrane signal transduction and second messenger responses. He followed up on this research interest as a Senior Staff Fellow in Laboratory Neurochemistry, National Institute on Aging, NIH, Bethesda, MD, investigating the use and development of unsaturated fatty acids for *in vivo* imaging of brain function in response to neuroactive challenges.

He joined the Center for Drug Evaluation and Research, FDA, as a pharmacology reviewer in the Division of Neuropharmacological Drug Products in 1989, then served as a supervisor for Pharmacology and Toxicology in the divisions Oncology and Pulmonary Drug Products, and eventually served as Associate Director for Pharmacology and Toxicology until 2002. In these roles he was responsible for developing and implementing national and international preclinical drug development guidance and functioned as the CDER/FDA Lead Safety Expert for carcinogenicity, safety pharmacology and chronic toxicity test guidelines within the International Conference of Harmonization.

In 2002 Dr. DeGeorge joined Novartis Pharmaceuticals Corporation where he served as Vice President, Preclinical Safety Evaluation; Global Head, Research and Development Safety Assessment. In 2004 Dr. DeGeorge joined Merck & Co. as Vice President, and currently serves as Worldwide Head of Safety Assessment.

Dr. Richard Fenske

Dr. Richard A. Fenske is Professor of Environmental and Occupational Health Sciences at the University of Washington (UW) and director of the NIOSH-supported Pacific Northwest Agricultural Safety and Health Center since its establishment in 1996. He is a core faculty member of the NIEHS-supported Center for Ecogenetics and Environmental Health. He also served as Deputy Director of the EPA/NIEHS-supported UW Center for Child Environmental Health Risks Research from 1998-2003, and Director of the UW Field Research and Consultation Group from 1992-1996. Dr. Fenske has focused his research on the assessment and mitigation of chemical hazards through workplace and community studies. He has developed new procedures for the assessment of skin exposure through the use of fluorescent tracers. He has also contributed to the elucidation of pesticide exposure pathways for children living in agricultural communities and in residential settings. His current research includes studies of pesticide spray drift, novel biomonitoring techniques, and para-occupational exposures of children in rural communities. He currently receives research support from the NIOSH Agricultural Centers Program, the EPA/NIEHS Children's Environmental Health Centers Program, and an EPA STAR grant.

Dr. Fenske currently serves on the U.S. Environmental Protection Agency's Science Advisory Board (Integrated Human Exposure Committee), and is also a member of the National Academy of Sciences/Institute of Medicine Committee to Review the Health Effects in Vietnam Veterans of Exposure to Herbicides.

From 1984-1990 Dr. Fenske was Assistant Professor and then Associate Professor of Environmental Sciences at Rutgers University. Prior to this position, he received his doctoral degree and master's in public health from UC Berkeley in Environmental Health Sciences. He was also awarded a master's degree in geography from UC Berkeley and a master's degree in comparative religion from Columbia University in New York. His bachelor's degree was in history from Stanford University.

Dr. Susan Fish

Dr. Susan Fish is Associate Professor of Biostatistics and Epidemiology at the Boston University School of Public Health. She is also the co-director of the MA in Clinical Research program at Boston University School of Medicine. Dr. Fish received her Doctor of Pharmacy degree from the University of Minnesota and her Masters of Public Health from Boston University, as well as a Bachelor's Degree in pharmacy from Massachusetts College of Pharmacy and Allied Health Sciences and a Bachelor's Degree in chemistry and education from the University of Massachusetts.

Dr. Fish previously held positions as Director of Human Subjects Protection and Associate Director of the Office of Clinical Research at Boston University Medical Center (BUMC), Director of the BUMC Institutional Review Board and Director of Research Participant Safety at the General Clinical Research Center at Boston University School of Medicine. She has also served as Director of Regulatory Affairs at CareStat, Inc, (a contract research organization) and as Vice Chair for Research in the Department of Emergency Medicine at Boston City Hospital/Boston Medical Center and Associate Professor of Emergency Medicine at Boston University School of Medicine. Prior to that, she was Associate Director of the Massachusetts Poison Control System and Associate Professor at Massachusetts College of Pharmacy and Allied Health Sciences. Dr. Fish has been a medical researcher for more than 20 years. She was a member of the Human Studies Committee at Boston City Hospital/Boston Medical Center from 1989-99 and served for five years as Associate Chair of the Committee. On the national level, Dr. Fish is an active member of many organizations, including the Society for Academic Emergency Medicine and PRIM&R (Public Responsibility in Medicine and Research) where she serves on the Board of Directors. In a variety of forums, Dr. Fish lectures on the design, conduct, and management of clinical trials, as well as research ethics and protection of human research subjects. She teaches courses at the Boston University Schools of Public Health and Medicine, and is frequently an invited speaker nationally. Although she has a long history of research in the areas of clinical toxicology and emergency medicine, Dr. Fish has most recently focused on research ethics in general, and application of the federal regulations for waiver of informed consent in certain emergency research circumstances. Her sabbatical project was consistent with this focus, working as Project Director for PRIM&R's Accreditation Project to develop a national accreditation system for human research protection programs.

Dr. Celia Fisher

Dr. Celia B. Fisher is the Marie Ward Doty Professor of Psychology and Director of the Fordham University Center for Ethics Education. Dr. Fisher is a member of the DHHS Secretary's Advisory Committee on Human Research Protections (SACHRP), Co-Chair of the

SACHRP Subcommittee on Research Involving Children, and founding editor of the journal *Applied Developmental Science*. She chaired the American Psychological Association's (APA) Ethics Code Task Force, the New York State Board for Psychology, the Ethics Committee of the Society for Research in Child Development, and the National Task Force on Applied Developmental Science*;* and is past member of the Ethics Working Group of the National Children's Study, the NIMH Data Safety and Monitoring Board, and the Institute of Medicine s Committee on Clinical Research Involving Children. Dr Fisher is author of *Decoding the Ethics Code: A Practical Guide for Psychologists* (Sage Publications), co-editor of 5 books including *Ethical Issues in Mental Health Research with Children and Adolescents* (Erlbaum Associates) and *The Handbook of Ethical Research with Ethnocultural Populations and Communities* (Sage Publications), author of over 100 publications in the areas of ethics and life-span development and of commissioned papers for the President's National Bioethics Advisory Commission on relational ethics and vulnerable populations and on the ethics of suicide research for NIMH. With support from NICHD she has studied how to assess and enhance research consent capacity of adults with developmental disabilities. With funding from NSF and NIH she has developed research ethics instructional materials for undergraduates, graduate students, senior scientists, and IRBs and examined parent-child perspectives on the ethics of adolescent risk research. Her current federally funded projects include Mentoring the Responsible Conduct of Research (ORI/NIAID), Participant Perspectives on Drug Use and Related HIV Research (NIDA) and the Fordham Alcohol Prevention Program (NIAAA). In July 2001 she co-chaired the APA, NIMH, and Fordham Ethics Center sponsored national conference on Research Ethics for Mental Health Science Involving Ethnic Minority Children and Youth (*American Psychologist, December 2002)*. In 2005 she chaired the APA meeting on Minimal Risk in Social Behavioral Research and co-chaired the Fordham Summit on Biopharmaceuticals for the 21st Century: Responsibility, Sustainability & Public Trust. She has developed assessment instruments to evaluate how teenagers and parents from different racial/ethnic backgrounds prepare for and react to racial discrimination, examined the validity of child abuse assessment techniques in institutional and forensic settings, and family attitudes toward involvement of adolescents in decisions to participate in pediatric cancer research.

Dr. Suzanne Fitzpatrick

Dr. Suzanne Fitzpatrick is a Senior Science Policy Analyst in the Office of the Commissioner, Office of Science and Health Coordination, at the US Food and Drug Administration. She is the Human Protection Administrator for the FDA Institutional Review Board. In this position, she drafted the Standard Operating Procedures for the FDA IRB and oversees its daily activities. She is also working on the oversight program for quality assurance of all FDA sponsored research. She is a member of the FDA Human Protection Steering Committee, the FDA Human Subjection Protection/Biomonitoring Steering Committee, and the 21 CFR 50.24 consultative review committee. Dr. Fitzpatrick is also a co-investigator on an FDA grant entitled "Pediatric Assent in Adolescent Research Participants" in collaboration with NCI/NIH and Walter Reed Army Medical Center. Dr. Fitzpatrick is the FDA National Environmental Protection Act (NEPA) liaison to the Council for Environmental Quality at the White House. She represents FDA on several Office of Science and Technology Policy Committees (OSTP) including the CNER Subcommittee on Toxics and Risk, the OSTP Subcommittee on Health and the

Environment, and the CNER Subcommittee on Endocrine Disruptors. She chairs, with EPA and USGS, the OSTP Interagency Working Group on Human and Veterinary Pharmaceutical in the Environment, whose charge is to leverage research strategies in this area across the different federal agencies. Dr. Fitzpatrick is also a member of the Interagency Committee on Validation of Alternative Animal Models. Dr. Fitzpatrick is a board certified toxicologist. She is the past president of the American College of Toxicology and also a past member of its board of councilors. Currently Dr, Fitzpatrick is the President Elect of the Nation's Capital Chapter of the Society of Toxicology (SOT), a Councilor for the Regulatory and Safety Specialty Section of and a member of the K-12 SOT Education Committee. She is also an adjunct professor at Johns Hopkins University, Zanvyl Krieger School of Arts and Science. Dr. Fitzpatrick received her BA from the University of California at San Diego and her PhD from Georgetown University.

Dr. Kannan Krishnan

Dr. Kannan Krishnan received his Ph.D. in Public Health from Université de Montréal, Canada and postdoctoral training from the Chemical Industry Institute of Toxicology (CIIT), Research Triangle Park, North Carolina. He is currently Professor of Occupational and Environmental Health and Director of the Human Toxicology research group (TOXHUM) at Université de Montréal. He has been the leader of the risk assessment methodologies theme team of the Canadian Network of Toxicology Centers (1994 – 2001), and Vice President of the Biological Modeling Specialty Section of the Society of Toxicology (2001-02). A member of the U.S. National Academy of Sciences (NAS) Sub-committee on Acute Exposure Guideline Levels (2001-2004), Dr. Krishnan is currently the president of the Risk Assessment Specialty Section of the Society of Toxicology and a temporary advisor for the World Health Organization. His expertise is in the areas of general toxicology, pharmacokinetics, physiologically-based modeling, chemical mixtures and health risk assessment methods. He has been a peer reviewer of several risk assessments, mixture risk assessment supplemental guidance and efforts on interactions for U.S. EPA. He has also been involved as a reviewer of toxicological profiles of chemicals and interaction profiles for chemical mixtures produced by ATSDR. An author of a text book on environmental pollution, Dr. Krishnan has authored or co-authored over 100 full-length publications in the areas of human health risk assessment, pharmacokinetics and its determinants in humans, chemical interactions in rodents and humans as well as computational toxicology. He has served on the editorial boards of *Toxicological Sciences*, *International Journal of Toxicology*, *Journal of Applied Toxicology* and *Journal of Child Health*. In the year 2000, he received the *Veylian Henderson Award* from the Society of Toxicology of Canada for significant contributions to the field of toxicology in Canada and was co-recipient of the *Best paper award (2003)* from the Board of Publications of the Society of Toxicology.

Dr. Krishnan's current research projects are funded by the Natural Sciences and Engineering Research Council of Canada. Past funding sources include Quebec Health Research Council, Canadian Network of Toxicology Centers, Health Canada and Ethylbenzene Panel of American Chemistry Council.

Dr. Kyung Mann Kim

Dr. Kim is Professor of Biostatistics and Statistics and Associate Chair of the Department of Biostatistics and Medical Informatics at the University of Wisconsin-Madison and Director of

Biostatistics Shared Resource at the University of Wisconsin Comprehensive Cancer Center. Prior to his current appointment, he was Assistant Professor (1988-1994) and Associate Professor (1994-1995) of Biostatistics at Harvard University and Dana-Farber Cancer Institute, Associate Professor of Biostatistics at the University of Michigan in Ann Arbor, MI and Director of Biostatistics at the University of Michigan Comprehensive Cancer Center (1995-1997), and Visiting Associate Professor of Ophthalmology at Johns Hopkins University (1995). Dr. Kim is recognized nationally and internationally for his contributions in statistical methods for interim analysis in clinical trials and clustered and repeated measures analysis and in clinical oncology research and has published extensively in statistical methods for clinical trials and in cancer clinical trials. He is Co-chair of the Protocol Review and Monitoring Committee and the Data and Safety Monitoring Committee of the University of Wisconsin Comprehensive Cancer Center, reviewing the scientific merit of clinical trial protocols, the safety of participants, and the scientific validity of data. He was a member of the Lung Cancer Concept Evaluation Panel, Division of Cancer Treatment and Diagnosis, National Cancer Institute (NCI) (1999-2002) and a member of Subcommittee E on Cancer Epidemiology, Prevention and Control, NCI Initial Review Group (2001-2005). He was a member of the Autoimmune Diseases Data and Safety Monitoring Board, National Institute of Allergy and Infectious Diseases (NIAID) (2000-2004) and has been serving as member of the HIV/AIDS Therapeutic Trials Data and Safety Monitoring Board, NIAID since 1998. These activities all relate to human studies review and ongoing review and monitoring of participant safety and study scientific validity in clinical trials. Dr. Kim was elected member of the Regional Committee of the Eastern North American Region (ENAR) of the International Biometrics Society and ENAR representative to the Biological Sciences Section of the American Association for Advancement of Science. He is an Associate Editor for Biometrics, an official journal of the International Biometric Society. He served as Founding Chair of the National Working Group of Cancer Center Biostatistics Directors during 1996-2003. He is Chair of the Program Committee for the Annual Meeting of the Society for Clinical Trials in 2006. He is a Fellow of the American Statistical Association. Dr. Kim received his Bachelor of Science (B.S.) degree in Computer Science and Statistics in 1978 and Master of Science (M.S.) degree in Statistics in 1980, both from Seoul National University, Seoul, Korea and Doctor of Philosophy (Ph.D.) degree in Statistics from the University of Wisconsin-Madison in 1985.

Dr. Lois Lehman-McKeeman

Dr. Lois Lehman-McKeeman is currently a Distinguished Research Fellow in Discovery Toxicology at the Bristol-Myers Squibb Company in Princeton, NJ. She received a BS degree in Toxicology from the Philadelphia College of Pharmacy & Science and holds a Ph.D. in Toxicology from the University of Kansas Medical Center. She was employed in the Human and Environmental Safety Division of the Procter and Gamble Company for 15 years prior to joining Bristol Myers Squibb in 2001. Lois has active research interests and programs broadly in mechanisms of toxicity, with emphasis on secondary mechanisms of carcinogenesis. She is also working to develop and apply metabonomic and transcriptomic technologies to mechanistic toxicology. She has been active professionally in the Society of Toxicology (SOT) serving on numerous SOT committees, and she held elective office in the SOT as Councilor from 2000-2002. In 2003 she was appointed Editor of Toxicological Sciences, a position she currently holds, and she serves on a number of other editorial boards. She has or is presently sitting on a variety of national and international advisory committees for EPA, NIH, IARC and IPCS. She is

a fellow in the Academy of Toxicological Sciences, and she was the recipient of the Robert Scala Award in Toxicology for research excellence in an industrial laboratory in 1994 and the Society of Toxicology Achievement Award in 2003.

Dr. Michael Lebowitz

Michael Lebowitz has a Ph.D. in, Epidemiology & International Health, and Environmental Health Sciences (with minors in Sociology and Biostatistics), and a Ph.C. in Preventive Medicine (with a minor in Biomedical Sciences) from the University of Washington (Seattle). He also has an MA in Biostatistics (with a minor in Demography) and a BA in Psychology from the University of California (Berkeley). He completed his clinical training in cardio-pulmonary medicine at the University of London Postgraduate Cardio-thoracic Institute. He started in public health in 1962, and worked in both county and state health departments in Epidemiology and Biostatistics.

His areas of expertise are environmental health sciences, occupational medicine, and chronic & infectious disease epidemiology. Dr. Lebowitz has served on the EPA Science Advisory Board, on National Academy of Sciences (NRC-NAS/IOM) committees, and has been a consultant and peer-reviewer for EPA, NIH, NIOSH and other agencies for over 30 years. He has also served as member/chair of committees for WHO, PAHO, and UNEP. He has been an expert consultant and witness for state and federal government agencies, various NGOs and CBOs. He has over 400 peer-reviewed publications.

He is a fellow of the American College of Chest Physicians, the American College of Epidemiology, and the Collegium Ramazzini. He is an elected member of the International Academy of Indoor Air Sciences, the American Epidemiological Society, the International Epidemiological Association, Delta Omega (the honorary public health society), and as an honorary member of the Hungarian Society of Hygiene. He is a founding member of the International Society of Exposure Analysis (ISEA) and the International Society of Environmental Epidemiology, and a charter member the Society of Epidemiological Research. He has been a member of other medical and scientific societies. He is a past President of ISEA and recipient of its highest award (the Wesolowski Award), and is past Chair of the national prevention research centers national program. He has been received various honors and awards from The University of Arizona College of Public Health and Graduate College. He has been Principal Investigator (PI) of many grants.

Dr. Jerry Menikoff

Dr. Jerry Menikoff is Associate Professor of Law, Ethics & Medicine and Director of the Institute for Bioethics, Law and Public Policy at the University of Kansas School of Medicine. Since 1998 he has served as chairperson of the Institutional Review Board at that institution. He is also currently Medical Director of Hospital Ethics at the University of Kansas Hospital, and an Associate Professor of Law at the University of Kansas School of Law. He received his undergraduate degree from Harvard University (magna cum laude in Mathematics, 1973), and also received in 1977 a J.D. (magna cum laude; Editor and Officer of the Harvard Law Review) and M.P.P. (Public Policy) from Harvard. Dr. Menikoff earned an M.D. in 1986 from Washington University (St. Louis). He served as a judicial clerk to the Honorable Irving R. Kaufman, Chief Judge, United States Court of Appeals for the Second Circuit, and has been a

faculty fellow at the MacLean Center for Clinical Medical Ethics at the University of Chicago, and at the Center for Ethics and the Professions at Harvard University.

For the past several years, Dr. Menikoff's research interests have concentrated on bioethics in general, and more particularly on the ethics of research with human subjects. His widely used textbook *Law and Bioethics: An Introduction* (Georgetown University Press 2001) is now in its second printing, and was chosen in 2002 by the Association of American University Presses as one of "The Best of the Best from the University Presses: Books You Should Know About." He is a coauthor of the recently published textbook (and accompanying teacher's manual), *The Ethics and Regulation of Research with Human Subjects* (LexisNexis 2005). His newest book, providing an evaluation of how the United States regulates research with human subjects, will be published in 2006 by Oxford University Press. He has on a number of recent occasions been hired as a consultant by the federal Office for Human Research Protections, and was one of the eight panelists convened by that agency to review the controversial issues raised by the ARDS Network studies (see Jeffrey M. Drazen, *Controlling Research Trials*, New Engl. J. Med. 2003;348:1377-80). He has recently written about the issues that led to the creation of the EPA Human Studies Review Board in *Of Babies, Bugs, and Bombast: A Look Behind the Crash-and-Burn of the CHEERS Pesticide Study*, 4(14) Medical Research Law & Policy Report 586 (BNA) (July 20, 2005), and is a member of the Advisory Board for the Medical Research Law & Policy Report.

Dr. Robert M. Nelson

Dr. Robert M. Nelson is Associate Professor of Anesthesiology and Critical Care at The Children's Hospital of Philadelphia (CHOP) and the University of Pennsylvania School of Medicine. After receiving his MD degree from Yale University in 1980, Dr. Nelson trained in pediatrics (Massachusetts General Hospital), neonatology and pediatric critical care (University of California, San Francisco). He has received formal training in theology, religious and medical ethics, receiving a Master of Divinity degree from Yale Divinity School in 1980 and a Ph.D. in The Study of Religion from Harvard University in 1993. Dr. Nelson has lectured and published widely on ethical and regulatory issues in pediatric research and clinical care. Dr. Nelson is Chair of the Pediatric Advisory Committee (PAC) of the Food and Drug Administration, and former Chair of the PAC Pediatric Ethics Subcommittee. He also serves as a member of the Subcommittee on Research Involving Children of the DHHS Secretary's Advisory Committee on Human Research Protections. Dr. Nelson was a member of the Committee on Clinical Research Involving Children of the Institute of Medicine (through March 2004), and former Chair of the Committee on Bioethics of the American Academy of Pediatrics (through 2001). Currently he is Director of the Center for Research Integrity, established at CHOP to further the responsible conduct of pediatric research. Dr. Nelson's current research explores different aspects of child assent and parental permission such as adolescent risk perception, the development of a child's capacity to assent, and the degree to which parental choice is perceived as voluntary. His research has been funded by the National Institutes of Health, the Greenwall Foundation and The National Science Foundation.

Dr. Sean Philpott

Dr. Sean Philpott is a tenured Research Scientist (Assoc. Research Professor) in the Department of Infectious Disease at the New York State Department of Health, an Adjunct Professor in the Department of Biomedical Sciences of the University at Albany School of Public Health, and is the Executive Managing Editor of the American Journal of Bioethics. He serves on the New York State Department of Health Institutional Review Board and is a member of the New York Working Group on Bioethics. He is involved in a Fogarty Institute-funded project to teach research ethics to Central and Eastern European scientists, physicians, lawyers and other professionals. Dr. Philpott also serves as consultant to various governmental and non-governmental bodies, such as the Forum for Collaborative HIV Research.

He received his undergraduate degrees in biology and medical anthropology from the University of California at San Diego, and completed his Ph.D. in Microbiology at the University of California at Berkeley. In addition to his on-going laboratory studies of HIV pathogenesis, Dr. Philpott is particularly interested in the ethical issues associated with biomedical research, including the protection of human subjects in industrialized and developing countries and the management of conflicts of interest in academia.

Dr. Richard Sharp

Dr. Richard R. Sharp (Ph.D. Philosophy, Michigan State University, 1999) is an Assistant Professor of Medicine with the Center for Medical Ethics and Health Policy, Baylor College of Medicine (BCM). Dr. Sharp's professional interests center on ethical issues in biomedical research and genetics. He has written on ethical considerations in testing asymptomatic persons for genetic predispositions to disease, understandings of race and ethnicity in genomic research, and the identification of genetic sensitivities to environmental toxicants. Dr. Sharp is the principle investigator for several ongoing research projects, including: 1) Indian and Hindu perspectives on genetic variation research, 2) Patient attitudes regarding the collection and use of biological materials for genomic research, 3) Patient perspectives on the role of consumer advocacy groups, and 4) Ethical, legal, and social issues in toxicogenomic research. Dr. Sharp directs the fourth course in the BCM Ethics Track, Research in Clinical Medical Ethics, and participates in the teaching of clinical ethics to medical students, residents, and clinical fellows at Ben Taub General Hospital and The Methodist Hospital. He also lectures on topics in research ethics in the Clinical Scientist Training Program and the Research Ethics Symposium, a training program on research conduct for clinical fellows, post-doctoral fellows, and graduate students in the biological sciences. Dr. Sharp coordinates Ethics Grand Rounds for The Methodist Hospital and serves on their Ethics Committee. Dr. Sharp has served on advisory committees for the American Thoracic Society, the European Respiratory Society, the Alpha One Foundation, the Woodrow Wilson Center, and the National Institutes of Health. Before joining the Center in 2002, Dr. Sharp worked as a Biomedical Ethicist at the National Institute of Environmental Health Sciences where he directed the Program in Environmental Health Policy and Ethics.