CURRICULUM VITAE

MICHAEL G. FARROW, Ph.D.

PRESENTLY

Dr. Farrow presently is providing consulting services in new product development in the food, drug, medical device and pesticide / chemical arenas enabling clients to provide the pertinent data to the proper regulatory agencies including the US FDA, the US EPA and the appropriate agencies in Europe and Japan.

Dr. Farrow's areas of special expertise include: comprehensive regulatory and compliance assistance pertaining to pharmaceuticals, chemicals, pesticides, foods, cosmetics, medical devices and biomaterials, and recombinant DNA products. Services include regulatory strategy, and planning, and development and interpretation of technical data including protocol design, laboratory selection and study monitoring, literature review, good laboratory practice audits, and packaging and submission of data in compliance with U.S. and international governmental guidelines. He has extensive experience in compiling INDs, NDAs, PMAs, and 510(k)s, arranging meetings with, and discussing issues with, appropriate governmental agencies. Dr. Farrow has worked closely with Clinical Research Organizations in the design and monitoring of clinical protocols. Dr. Farrow also provides assistance in EPA submissions such as LVEs and PMAs and New Substance Notifications for Canada as well as regulatory strategy for compliance with State and Federal EPA regulations.

PREVIOUSLY

Director of Toxicology, Experimental Pathology Laboratories, Inc., Herndon, Virginia
(1984-1985)

Responsible for directing programs to monitor, audit, and evaluate safety evaluation studies in the fields of toxicology, pathology, teratology, and mutagenicity. Responsible for business development in related areas, market research and client consultation in the development of testing strategy.

Hazleton Laboratories
(1983-1985)

Director of In Vitro Program Development, Hazleton Biotechnology Corporation, Vienna, Virginia

Responsible for directing program development in genetic toxicology, medical devices, and biomaterials. Responsible for developing testing programs in in vitro teratology, immuno-

toxicology, in vitro toxicology, and neurotoxicology. Served as director of corporate-wide research program.

Director, Genetic Toxicology Laboratory, Hazleton Laboratories America, Inc., Vienna, Virginia

Responsible for directing programs to evaluate chemicals, drugs and particulates in assays designed to determine potential mutagenic or carcinogenic risk. Studies included *in vivo* and *in vitro* assays utilizing bacteria, mammalian cells, and insects to detect gene mutations, chromosomal damage, and DNA damage and repair. Directed the *in vitro* teratology program and, in addition, coordinated the medical device and biomaterials testing program which included assays in cytotoxicity, microbiology, acute toxicology, and chemistry and clinical trials.

Director of Toxicology, JRB Associates, McLean, Virginia
(1978-1981)

As a senior health staff member of this management and consulting firm, provided consulting services to industry and the Government. Evaluated relevant literature on toxic effects of environmental and workplace chemicals, military compounds, and consumer products, and reviewed and analyzed data concerning human and animal teratogenesis, carcinogenesis, and mutagenesis.

Based on knowledge of the regulatory requirements of various agencies of the Federal Government including EPA, NIOSH, OSHA, CPSC, FDA, and DOE, recommended the placement of animal studies for industry and the Government. Advised clients on study requirements and design to obtain approval of their products by the federal regulatory agencies. Applied guidelines from CDC, NCI, OSHA, and NIOSH; provided consultation to architectural firms in designing or remodeling toxicological, biological, and chemical laboratories for chemical, pharmaceutical, and academic institutions with emphasis on minimizing occupational hazards associated with the testing or use of hazardous substances such as nitrosamines, known carcinogens and mutagens, toluene, radioactive materials, and particulate matter. Established a new laboratory in mutagenicity with expansion plans to include toxicology. Other duties included budgeting, marketing, staffing, design and expansion as well as scientific programming, review, and quality assurance.

Senior Pharmacologist, Wyeth Laboratories, Paoli, Pennsylvania
(1971-1978)
Assistant Director, Toxicology
(1975-1978)

Conducted pre-clinical tests to determine the toxicologic effect of chemicals and drugs on bacteria, animals, and humans. Responsible for identifying toxic or otherwise hazardous substances in final product formulation and conducted standard acute, subacute, and chronic toxicologic studies with rodents, dogs, swine and monkeys; teratologic and reproduction

studies; long and short term carcinogenic and mutagenic studies including bacteriological assays, chromosome cytogenetics, micronucleus assay, dominant lethal test, unscheduled DNA synthesis and repair and drosophila. Established the initial battery of industrial tests in neuro/behavioral teratology to determine the effects of toxic substances on the behavior of animals in the first generation.

Responsible for monitoring, analyzing and inspecting safety evaluation studies conducted by commercial research laboratories under contract to Wyeth Laboratories. Interpreted data and prepared reports for government and management and developed protocols and procedures required by the Food and Drug Administration.

Developed expertise in the application of governmental guidelines for Good Laboratory Practice and implemented the toxicologic guidelines of the United Kingdom, Japan, and the Common Market.

Genetic Counselor, West Virginia University Medical School, Morgantown, West Virginia.
(1966-1971)

Evaluated clinical protocols, conducted investigative research on chemotherapeutic agents, and counseled in human genetics, worked with state social service / adoption agencies to evaluate the racial makeup of newborns offered for adoption, assembled genetic pedigrees, karyotyped and evaluated chromosomes, taught undergraduate classes and laboratories in human genetics and presented lectures to junior and senior high school students, college students, and civic associations.

EDUCATION

Postdoctorate, Pbarmacogenetics	West Virginia University Medical School Morgantown, West Virginia, 1971
Ph.D., Human Genetics	West Virginia University Medical School Morgantown, West Virginia, 1971
Advanced Research, Epidemiology	University of Pittsburgh, Population Genetics Pittsburgh, Pennsylvania, 1966
M.S., Genetics	West Virginia University, Morgantown, West Virginia, 1964
B.S., Biology	Juniata College, Huntingdon, Pennsylvania, 1961

BIOGRAPHICAL LISTINGS

Who's Who (Southern Edition)

PROFESSIONAL SOCIETY MEMBERSHIPS

American College of Toxicology	(Past Treasurer)
American Genetic Association	
Behavioral Teratology Society	
Environmental Mutagen Society	
European Teratology Society	
Japanese Teratology Society	
Genetic Toxicology Association	(Past Chairman & Founder)
Mid-Atlantic Reproduction and Teratology Association	(Past President)
Sigma Xi	
Society for Risk Assessment	
Teratology Society (USA)	
National Capital Area Chapter - Society of Toxicology	(Past President)
Regulatory Affairs Professionals Society	(RAC Certified)

PUBLICATIONS

Farrow, M.G. and V. Ulrich, X-Ray and Gamma Ray Irradiation of Mormoniella vitripennis, Proc. West Virginia Acad. Sci., 35, 21-28, 1963.

Farrow, M.G. and R.C. Juberg, Genetics and Laws Prohibiting Marriage in the United States, JAMA, 209, 534-538, 1969.

Farrow, M.G. and K. Van Dyke, Microsystem for Measurement of Anti-Leukemic Drugs Utilizing Human Whole Blood, Chemotherapy, 16, 76-84, 1971.

Farrow, M.G. and V. Ulrich, Chromatographic and Fluorometric Analysis of Sepia and Mutant Eye Colors in Mormoniella vitrivennis, Pro. West Virginia Acad. Sci., 43, 67-71, 1971.

Farrow, M.G., A. Hawk, L. Wetzel and G.C. Boxill, A Microculture Technique Utilizing Whole Blood for Mouse Chromosome Analysis, Mutation Research, 26, 401-405, 1974.

Farrow, M.G., D.F. Blaydes and K. Van Dyke, The Effect of Plant Growth Substance and Natural Products on RNA, DNA Synthesis in Leukocytes, Experimentia, 32(l), 29-30, 1975.

Legator, M.S. (Group Leader), E. Bueding, R. Batzinger, T.H. Connor, E. Eisenstadt, M.G. Farrow, G. Ficsor, A. Hsie, J. Seed, and R.S. Stafford, An evaluation of the host-mediated assay and body fluid analysis, A report of the U.S. Environmental Protection Agency Gene-Tox Program. Mutation Research, 98, 319-374, 1982.

Cortina, T.A., E.W. Sica, N.E. McCarroll, W. Coate, A. Thakur, and M.G. Farrow, Inhalation Cytogenetics in Mice and Rats Exposed to Benzene in Proceedings of the Symposium on The Toxicology of Hydrocarbons, pp. 122-127, H.N. MacFarland, C.E. Holdsworth, J.A. MacGregor, R.W. Call, and M.L. Kane (editors), American Petroleum Institute, Washington, DC, 1982.

Cortina, T.A., E.W. Sica, N.E. McCarroll, W. Coate, A. Thakur, and M.G. Farrow, Inhalation Cytogenetics in Mice and Rats Exposed to Benzene, pp. 81-89, Advances in Modern Environmental Toxicology, M.A. Melman (series editor), Vol. 6, Princeton Scientific Publishers, Inc., Princeton, NJ, 1984.

McCarroll, N.E., M.G. Farrow, H. Scribner, and K. McCarthy, A Survey of Genetic Toxicology Testing in Industry, Contract Laboratories, and Government, Journal of Applied Toxicology, Vol. 4(2), 66-74, 1984.

PAPERS PRESENTED

Farrow, M.G., N.E. McCarroll, A.E. Auletta, 1984 Survey of Genetic Toxicology Testing in Industry, Government, and Academic Laboratories, J. Appl. Toxicol. 6(3), 221-223, 1986.

Farrow, M.G., Unique Aspects of GLP Pathology, J. American College of Toxicol. 6(2), 207-211, 1987.

Salem, H. and M.G. Farrow (eds.) Selected Nuisance Dusts: Are Short Term Tests Predictive?, J. Appl. Toxicol. 8(6), 379403, 1988.

Auletta, A.E. and M.G. Farrow, 1986 Survey of Genetic Toxicology Testing in Industry, Government, and Academic Laboratories in press.

ABSTRACTS

Farrow, M.G. and K. Van Dyke, A Microsystem for Measurement of Anti-Nucleic Acid, Anti-Leukemic Drug Effects in Developing Human Chromosomes, Pharmacologist, 12(2), 1970.

3

Farrow, M.G., Stimulation of Incorporation of Uridine-5- H into RNA OtHuman White Cells by a Amanitin, Fed. Proc., 30(2), 1971.

Farrow, M.G., D. Blaydes and K. Van Dyke, The Effect of Plant Growth Substances and Natural Products on RNA, DNA Synthesis in Leukocytes, Pro. West Virginia Acad. sci., 45(2), 164, 1973.

Farrow, M.G., A. Hawk, L. Wetzel and G.C. Boxill, A Method for Culturing Peripheral Blood Leukocytes for *Chromosome* Analysis in the Dog, Guinea Pig, Hamster, Monkey, Mouse and Rat, Mutation Research, 28, 145-146, 1975.

Farrow, M.G., The Use of Tremethyphosphate (TMP) as a Positive Control Agent in the Dominant Lethal, Cytogenetic and Host-Mediated Assays, Mutation Research, 31(5), 314-315, 1975.

Farrow, M.G., J. Barnett. L.J. Lassen and L. Wetzel, The Use of Trimethyphosphate (TMP) as a Positive Control Agent. II. The almonella/microsome test; the Salmonella/urine assay and the micronucleus test, Mutation Research, 38, 381-382, 1976.

Farrow, M.G., D.F. Blaydes and K. Van Dyke, Plant Flavonoids and Nucleic Acid Synthesis in Human Leukocytes. Ohio J. Sci., 79(6), 283-284, 1979.

McCarroll, N.E., C.E. Piper, H. Padilla-Nash, B.H. Keech, and M.G. Farrow, Genotoxicity of n-Hexane, presented at the Third International Conference on Environmental Mutagens, Tokyo, Japan, 1981.

Keech, B.H.,N.E. McCarroll, and M.G. Farrow, Increasing the Sensitivityof Microsuspension Assays by Using Three Bacterial DNARepair Systems, presented at the 13th Annual Meeting of the Environmental Mutagen Society, Boston, Massachusetts, 1982.

Farrow, M.G., Methodological Aspects of Cytogenetics, presented at the Workshop on Principles and Applications of Cytogenetics, Sister Chromatid Exchange, Gene Damage,Unscheduled DNA Synthesis, to Problems of Human Health, sponsored by the American College of Toxicology, Fredericksburg, Virginia, 1982.

Farrow, M.G., N. McCarroll, T. Cortina, M. Draus, A. Munson, M. Steinberg, C. Kirwin and W. Thomas, In Vitro Mutagenicity and Genotoxicity of Fuels and Paraffinic Hydrocarbons in the Ames, Sister Chromatid Exchange, and Mouse Lymphoma Assays, presented at the 22nd Annual Meeting of the Society of Toxicology, Las Vegas, Nevada, 1983.

Farrow, M.G. and B.H. Keecb, Chinese Hamster Ovary Cells (CHO) Clonal Growth Assay for the Evaluation of Cytotoxic Effects, presented at the Second World Congress on Biomaterials, Washington, DC, 1984.

Sernau, R., T. Cortina, M. Zito, N. McCarroll and M.G. Farrow, Genotoxicity of Asbestos and Fiberglass in the Chinese Hamster Ovary (CHO) HGPRT Forward Mutation, and Sister Chromatid Exchange Assays, presented at the Environmental Mutagen Society Meeting, Montreal, Canada, 1984.

Draus, M.A., Kennedy, E.M., Tait, J.D., and Farrow, M.G., A Comparison of Two in vitro Assays for the Evaluation of Teratogenic Potential, presented at the Environmental Mutagen Society Meetings, Montreal, Canada, 1984.

NATIONAL INSTITUTE OF OCCUPATIONAL SAFETY AND HEALTH

Author, Toxicology Chapter, Pesticides, Criteria Document Prepared for the National Institute of Occupational Safety and Health, Rockville, Maryland, 1977-78.

Author,Toxicology Chapter, welding and Brazing, Criteria Document. Prepared for the National Institute
of Occupational Safety and Health, Rockville, Maryland, 1978-79.

Author, Toxicology Chapter, Coal Liquifaction, Criteria Document. Prepared for the National Institute of Occupational Safety and Health, Rockville, Maryland, 1978-79.

Author, Toxicology chapter, Foundries, Criteria Document. Prepared for the National Institute of Occupational Safety and Health, Rockville, Maryland, 1978-79.

Author, Toxicology Chapter, Methyl Chloride, Criteria Document. Prepared for the National Institute of Occupational Safety and Health, Rockville, Maryland, 1978-79.

Author, Toxicology Chapter, Nitrotoluenes, Criteria Document. Prepared for the National Institute of Occupational Safety and Health, Rockville, Maryland, 1978-79.

Author, Toxicology Chapter, Wood Preserving, Criteria Document. Prepared for the National Institute of Occupational Safety and Health, Rockville, Maryland, 1979-80.

Author, Toxicology Chapter, Aliphatic, Di and Polyamines, Criteria Document Prepared for the National Institute of Occupational Safety and Health, Rockville, Maryland, 1979-80.

Author, Toxicology Chapter, Monochloroethane, Criteria Document. Prepared for the National Institute of Occupational Safety and Health, Rockville, Maryland, 1979-80.

Author, Toxicology Chapter, Pentachloroethane, Criteria Document. Prepared for the National Institute of Occupational Safety and Health, Rockville, Maryland, 1979-80.

Author, Toxicology Chapter, Hexachloroethane, Criteria Document. Prepared for the National Institute of Occupational Safety and Health, Rockville, Maryland, 1979-80.

Author, Toxicology Chapter, Tetrohydrofuran, Criteria Document. Prepared for the National Institute of Occupational Safety and Health, Rockville, Maryland, 1979-80.

ENVIRONMENTAL PROTECTION AGENCY HAZARD ASSESSMENT DOCUMENTS

Contributing Author, Assessment of Testing Needs: Clorinated Benzenes. Support Document for proposed Health Effects Test Rule Toxic Substances Control Act Section 4. Prepared for the Environmental Protection Agency, Washington, DC, 1980.

Contributing Author, Assessment of Testing Needs: Clorinated Paraffins. Support Document for Proposed Health Effects Test Rule Toxic Substances Control Act Section 4. Prepared for the Environmental Protection Agency, Washington, DC, 1980.

Contributing Author, Assessment of Testing Needs: Clorinated Napthalenes. Support Document for Proposed Health Effects Test Rule Toxic Substances Control Act Section 4. Prepared for the Environmental Protection Agency, Washington, DC, 1980.

Contributing Author, Assessment of Testing Needs: Nitrobenzenes. Support Document for Proposed Health Effects Test Rule Toxic Substances Control Act Section 4. Prepared for the Environmental Protection Agency, Washington, DC, 1980.

Contributing Author, Assessment of Testing Needs: Dichloromethane.Support Document for Proposed Health Effects Test Rule Toxic Substances Control Act Section 4. Prepared for the Environmental Protection Agency, Washington, DC, 1980.

Contributing Author, Assessment of Testing Needs: Cresols. Support Document for Proposed Health Effects Test Rule Toxic Substances Control Act Section 4. Prepared for the Environmental Protection Agency, Washington, DC, 1980.

Contributing Author, Assessment of Testing Needs: Dichloropropane. Support Document for Proposed Health EffectsTest Rule Toxic Substances Control Act Section 4 Prepared for the Environmental Protection Agency, Washington, DC, 1980.

Contributing Author, Assessment of Testing Needs: Pyridine. Support Document for Proposed Health Effects Test Rule Toxic Substances Control Act Section 4. Prepared for the Environmental Protection Agency, Washington, DC, 1980.

Contributing Author, Assessment of Testing Needs Hexachlorobutadiene. Support Document for Proposed Health EffectsTest Rule Toxic Substances Control Act Section 4. Prepared for the Environmental Protection Agency, Washington, DC, 1980.