

M.E. Ginevan & Associates, LLC

Statistical Consultation and Mathematical Modeling for the Health and Environmental Sciences

Michael E. Ginevan, Ph.D. Principal Scientist

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Professional Profile

Dr. Michael E. Ginevan is the President of M.E. Ginevan and Associates, LLC. Dr. Ginevan has more than 35 years experience in the application of statistics and computer modeling to problems in public health and the environment and in the conduct of environmental, epidemiologic, and risk assessment studies. He is the author of “Statistical Tools for Environmental Quality Measurement,” and over 70 other publications in the areas of statistics, computer modeling, epidemiology, and environmental studies.

In addition to his broad statistical background, he has had extensive training and research experience in the biological sciences, including epidemiology, exposure science, ecology, and genetics. He has also been an effective interdisciplinary project leader and manager in academia, government, and private industry, and in a diversity of problem areas, including biostatistics, epidemiology, toxicology, risk assessment, and environmental monitoring. Dr. Ginevan is adept at making intricate statistical analyses understandable to persons with relatively little mathematical knowledge and is effective in communicating complex scientific issues to lay audiences.

Dr. Ginevan is a founder and past Secretary of the American Statistical Association (ASA) Section on Statistics and the Environment, a recipient of the Section's Distinguished Achievement Medal, and a past Program Chair of the ASA Conference on Radiation and Health. He is a Charter Member of the Society for Risk Analysis. He has served on numerous review and program committees for ASA, the U.S. Department of Energy, the U.S. Nuclear Regulatory Commission, the National Institute for Occupational Safety and Health, the National Cancer Institute, and the U.S. Environmental Protection Agency. He also served as a member of the National Academy of Sciences Committee on Health Risks of the Ground Wave Emergency Network.

Credentials and Professional Honors

Ph.D., Mathematical Biology, University of Kansas, 1976
M.S., Zoology, University of Massachusetts at Amherst, 1971
B.S., Biology, State University of New York at Albany, 1968

Distinguished Achievement Medal, American Statistical Association Section on Statistics and the Environment, 1993; Sigma Xi, 1978; University of Kansas Dissertation Fellowship, 1975.

Michael Ginevan, Ph.D.

Prior Experience

Principal Scientist, Exponent, 2004-2006

Vice President and Principal Scientist, Blasland Bouck and Lee Inc., 2002–2004

Principal, M.E. Ginevan & Associates, 1991–2002

Deputy Director, Office of Epidemiology and Health Surveillance, United States Department of Energy, 1991–1993

Principal Scientist, Biostatistics and Epidemiology, RiskFocus Division, Versar Inc., 1990–1991

Senior Scientist, Biostatistics and Epidemiology, RiskFocus Division, Versar Inc., 1988–1990

Senior Science Advisor, Biostatistics, Environ Corporation, 1987–1988

Biostatistician, United States Nuclear Regulatory Commission, 1982–1986

Assistant Statistician and Group Leader, Human Health Risk Analysis Group, Division of Biological and Medical Research, Argonne National Laboratory, 1978–1982

Research Associate, Environmental Research Laboratory, Center for Research Inc., University of Kansas, 1976–1978

Professional Affiliations

- American Association for the Advancement of Science, (member, 1975–present)
- American Statistical Association, (member, 1976–present)
- Sigma Xi, (member, 1975–present)
- Society for Epidemiologic Research, (member, 1983–present)
- Society for Risk Analysis, (Charter Member)
- Society for Toxicology and Applied Pharmacology, (member, 2000-present)
- The Toxicology Forum (member, 2009-present)
- International Society of Exposure Science (member, 2013-present)

Consulting and Advisory Appointments

- Member, Board of Directors, The Toxicology Forum (2016-)
- Peer Reviewer, Mickey Leland National Urban Air Toxics Research Center (2008-2010)
- Peer Reviewer, EPA Superfund Preliminary Remediation Goals for Radionuclides in Outdoor Surfaces (SPRG) Electronic Calculator (2008)
- Peer Reviewer, EPA draft guidance document entitled: “Guidance for choosing a sampling design for Environmental Data Collection (EPA QA/G-5S)” (2001)
- Program Chair Elect/Program Chair: American Statistical Association Section on Risk Analysis (1999–2001)
- Member, Strategic Planning Committee, ASA Section on Statistics and the Environment (1994–1995)
- Member, Planning Committee, 11th ASA Conference on Radiation and Health (1993–1994)

Michael Ginevan, Ph.D.

- Member, Steering Committee, ASA/NSF Ethics and Statistical Experts Project (1993–1995)
- Councilor, Washington Area Chapter, Society for Risk Analysis (1990–1992)
- Secretary, ASA Section on Statistics and the Environment (1990)
- Member, Planning Committee, 9th ASA Conference on Radiation and Health (1989–1990)
- Chairman, 8th ASA Conference on Radiation and Health (1987–1989)
- Vice Chairman, ASA Committee on Statistics and the Environment (1987–1989)
- Member, ASA Committee on Nuclear Regulatory Research (1985–1990)
- Vice Chairman, 7th ASA Conference on Radiation and Health (1986–1987)
- Member (representing the Society for Risk Analysis), Planning Committee for the 9th Symposium on Statistics, Law, and the Environment (1986)
- Consultant, Tabershaw Occupational Medicine Associates, Study design: occupational health study of workers exposed to low level electromagnetic fields (1981)
- Member, Peer Oversight Committee, U.S. Environmental Protection Agency Terrestrial Biomonitoring Program (1978–1981)
- Planning Group, U.S. Environmental Protection Agency Terrestrial Biomonitoring Program (1977)
- Consultant, Kansas State Attorney General's Office, Furnished advice and testimony on quantitative and ecological aspects of environmental litigation (1977–1978)

Science Advisory Boards/Panels

- Member, National Research Council, Committee on Health Risks of the Ground Wave Emergency Network (1990–1993)
- Consultant, U.S. Environmental Protection Agency, Science Advisory Board, Radiation Advisory Committee. Review of the Multi-Agency Radiological Laboratory Analytical Protocols Manual (MARLAP) (2002–2003)
- Consultant, U.S. Environmental Protection Agency, Science Advisory Board, Radiation Advisory Committee. Review of the Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM) (1996–1998)
- Member, Radon Mitigation Subcommittee, U.S. Environmental Protection Agency, Science Advisory Board, Radiation Advisory Committee (1987–1989)

Editorships and Editorial Review Boards

- Editorial Board, *Regulatory Toxicology and Pharmacology* (1996–present)
- Associate Editor, *Environmental and Ecological Statistics* (1994–1998)

Michael Ginevan, Ph.D.

Peer Reviewer

- *Environmental Health Perspectives*
- *Regulatory Toxicology and Pharmacology*
- *Environmental and Ecological Statistics*
- *Environmetrics*
- *Science*
- *American Statistician*
- *Risk Analysis*
- *Environmental Science and Technology*
- *American Journal of Epidemiology*
- *Photogrametric Engineering and Remote Sensing*

Experience Summaries

Expert Testimony and Litigation Support

Dr. Ginevan has provided affidavits, expert reports, and both deposition and trial testimony in a broad array of matters. These include:

- Evaluation of patient demographic data, Medicare claims data, and medical test data for cardiac catheterizations from a cardiology practice in Texas. Analyses showed that the population being treated in the practice had a high burden of pre-existing disease, and that the frequency of false positive results in the cardiac catheterizations was similar to that in other medical practices in the area and was also similar to national rates. Taken together these facts showed that claims, from both the State and Federal Governments, of overbilling Medicare, had no factual basis.
- Evaluation of dioxin data and sampling protocols in Nitro, West Virginia. Analyses showed that plaintiff data did not demonstrate either pervasive dioxin contamination in the Nitro area or significantly elevated dioxin exposures in Nitro residents.
- Evaluation of formaldehyde sampling protocols, formaldehyde levels and potential exposures to persons, displaced by Hurricane Katrina, who resided in FEMA trailers. These analyses demonstrated that there was little evidence of high exposures in occupied trailers and suggested a number of deficiencies in plaintiff sampling protocols.
- Evaluation of contamination in buildings near the World Trade Center (WTC) disaster site. The allegation was that the buildings had to be demolished because they were contaminated at a level that would preclude remediation. Analysis showed that much of the contamination was preexisting and had nothing to do with the WTC disaster.
- Evaluation of biotechnology data to determine whether certain patented protocols produced higher transformation efficiencies. The conclusion was that the patented protocols conferred no advantage.
- Evaluation of the relative success of cattle embryo implantation using different types of syringe. This analysis showed that when the initial quality of embryos was taken into account, the allegedly defective syringe was no different, in terms of implantation success, than other models of syringe that had been used for the same purpose.

Michael Ginevan, Ph.D.

- Evaluation of PCB risks from consumption of fish from Watts Bar Lake. This evaluation showed that the risks from fish consumption were small and were far exceeded by the risks involved in catching said fish.
- Evaluation of respiratory disease complaint data from plaintiffs who lived in allegedly “sick” buildings. This analysis showed that the frequency of respiratory disease was no higher in the plaintiffs than in the general population.
- Evaluation of cancer risk modeling done by a plaintiff’s expert plus evaluation of environmental sampling data from a different plaintiff’s expert. These evaluations showed that claims of excess cancer risk from ethylene dibromide in ground water had no scientific basis.
- Analysis of water quality data that showed that a riverside feedlot was contaminating the river.

Dr. Ginevan has also provided non-testifying litigation support in numerous cases. Much of this work is conducted under confidentiality agreements, but general areas include evaluation of both plaintiff and defense expert reports to identify both factual and quantitative shortcomings, evaluation of the potential size of plaintiff classes based on the alleged disease entities and exposures, evaluation of the quantitative credibility of plaintiff claims using quantitative risk and exposure modeling, and identifying key quantitative strategies that can be used in defense efforts.

Statistical Research

- Analyzed the effect standardization of chemical concentration data has on subsequent Principal Component and other multivariate analyses of these data. These analyses showed that standardization distorts the information in the data and should not be used.
- Investigated the impacts that logarithmic dose transformation can have on analyses of epidemiologic data.
- Evaluated statistical strategies for apportioning the risks due to multiple environmental exposures.
- Developed procedures based on log-ratio statistics for evaluation of the likely sources of environmental contaminants. This work was published in a book chapter entitled “Statistical Tools for Ratio Data” in the book *Introduction to Environmental Forensics*.
- Developed lifetable-based modeling tools for prediction of the risks of less-than-lifetime and intermittent exposures to asbestos, radiation, and other carcinogens and for the evaluation of the relative contributions of cigarette smoking and radon exposure to subsequent lung cancer risk.
- Formulated new statistical methods for estimation of benchmark doses for cholinesterase inhibitors to aid regulatory decision making on organophosphorus pesticides.
- Proposed new methods for exploratory analysis of time-series based epidemiology data for use in estimating the health effects of air pollution.
- Defined advanced bootstrap methods for confidence intervals and hypothesis tests involving non-normal distributions for environmental contamination and human exposure data, and has developed analytic tools for the planning of Monte Carlo simulation studies.
- Developed procedures for evaluating environmental data when large numbers of observations are non-detects.

Michael Ginevan, Ph.D.

- Developed risk-based methods for planning the sampling and remediation of hazardous waste sites.
- Defined new modeling methodology for the prediction of toxicological equivalence factors for PCB's and dioxins.
- Developed robust regression methods for use in cross-sectional epidemiologic studies.
- Defined new procedures for the comparison of death rates across populations.
- Developed statistical techniques for the evaluation of environmental radiation survey data and procedures for the reconstruction of nuclear worker dosimetry.

Exposure Assessment

- Evaluated the impact of concentrations of pesticide metabolites on exposure estimates for organophosphorous pesticides.
- Conducted exposure studies for assessing exposure of Allied troops and civilian populations to Agent Orange and dioxin as a result of defoliation missions conducted during the Vietnam War.
- Evaluated formaldehyde concentration data from FEMA trailers used after Hurricane Katrina to determine the probable formaldehyde exposures to residents of these trailers.
- Evaluated the proposed methodology for assessing exposure of Allied troops to Agent Orange and dioxin as a result of defoliation missions conducted during the Vietnam War.
- Evaluated radiation exposures resulting from cleaning drill pipe used in the oil industry.
- Evaluated possible carcinogen exposures to workers in two manufacturing facilities.
- An author and reviewer for the book "Residential Exposure Assessment: A Sourcebook" and an author and reviewer for the book "Occupational and Residential Exposure Assessment for Pesticides."
- For the Agricultural Reentry Task Force, analyzed exposure data for agricultural workers and developed predictive models for worker exposure.
- Developed models for residential exposure resulting from pesticide use for two major pesticide industry task forces including analysis of patterns of pesticide deposition in indoor environments and development of Monte Carlo methods for prediction of the distribution of pesticide use events over time. This work was also presented as part of a workshop on Monte Carlo methods for predicting exposure over time at the 1998 Society for Risk Analysis Annual Meeting.
- Developed statistical protocols for chamber based exposure experiments in the pesticide industry to provide data for predictive models of human exposure resulting from contacts with indoor surfaces.
- Worked with the Federal Aviation Administration to develop exposure models for tobacco smoke and other pollutants aboard airliners.
- Worked with the Center for Indoor Air Research to develop improved exposure models for indoor air pollution resulting from environmental tobacco smoke (ETS). This effort included analysis of a large 16-city study database, collected by Oak Ridge National Laboratory, of exposure to ETS in both the work and home environment. These analyses were focused on developing markers of exposure and on describing personal characteristics that influence exposure levels. As a part of the second phase of this study, developed Monte Carlo models for ETS exposure in both the home and work environments.

Michael Ginevan, Ph.D.

- At the U. S. Department of Energy, started the Radiation Dosimetry Working Group to develop comparable dosimetric paradigms across the various radiation worker cohorts and worked with the industrial hygiene departments at a number of national labs to develop chemical exposure metrics for DOE workers.
- Worked with the Chemical Manufacturers Association on a major project to develop Monte Carlo methods for exposure assessment for chemicals in the environment.
- At the U.S. Nuclear Regulatory Commission, evaluated dosimetry data from civilian nuclear power plant workers and analyzed historical uranium miner data to reevaluate dosimetry estimates in these workers.
- Worked with the staff of the Center for Human Radiobiology at Argonne National Laboratory to develop models for radon exposure in radium dial painters.

Epidemiology

- Review of epidemiologic studies of Vietnam veterans to determine the extent to which adverse health effects are associated with herbicide exposure. Co-author of an extensive review of the Air Force Health Study of Veterans who were involved in Operation Ranch Hand, which was the major herbicide spray program for the Vietnam War.
- Reviewed the alleged association between intrauterine phthalate exposure and reduced anogenital distance in human male infants. Showed that the alleged association was the result of faulty quantitative analysis.
- Reviewed the epidemiologic literature on the association between the use of the Cox-2 inhibitors Celebrex and Bextra and heart attacks.
- Conducted extensive reviews of literature on asbestos exposure and subsequent risks of lung cancer and mesothelioma.
- Reviewed a variety of epidemiologic topics, including the effects of pesticide exposure on human health, cancer risks of electric field exposure and studies of the cancer risk associated with water chlorination.
- Performed epidemiologic investigations of the possible association between particulate air pollution and human health, and of cancer clusters in occupational exposure settings.
- Provided a comprehensive review of an occupational epidemiology study of cancer and exposure to radiation and chemicals conducted at the Rocketdyne Division of Boeing North American and assisted Boeing in presenting the results of this review to their workers.
- Served as Deputy Director of the Office of Epidemiology and Health Surveillance at the U. S. Department of Energy (DOE). Developed a blueprint for the DOE Health Surveillance System and lead the effort to complete the DOE Comprehensive Epidemiologic Data Resource (CEDR). Participated in "rapid response studies" of alleged cancer clusters and alleged sick building syndrome at DOE facilities.
- Served as the principal expert in epidemiology at the U.S. Nuclear Regulatory Commission (NRC). Investigated claims of cancer clusters alleged to have been caused by nuclear power plants. Developed protocols for epidemiology studies of nuclear power plant workers and, using data from uranium miners, modeled the risks of lung cancer caused by exposure to radon daughters (radioactive materials) and cigarette smoking.
- Conducted statistical evaluations of case-control studies of leukemia and diagnostic X-rays.
- Conducted a cross-sectional study of environmental pollution and human birth weights.

Michael Ginevan, Ph.D.

- Provided a comprehensive review of the epidemiology literature on the effects of electromagnetic fields on human health as an author of the National Research Council Report, "Assessment of the Possible Health Effects of Ground Wave Emergency Network".

Risk Analysis and Probability of Causation Evaluations

- Coauthor of a paper on methods of risk apportionment for multiple potential causal factors.
- Conducted an extensive risk assessment of the relationship between the presence of soft drink vending machines in schools and the risk of obesity in the student population. This work was published in the journal *Risk Analysis*.
- Developed life-table based models to evaluate the relative contribution of asbestos exposure at different times in life to subsequent risks of lung cancer and mesothelioma.
- Extensive involvement in the analysis of toxicological data sets and in cancer risk modeling for toxic materials.
- Evaluated data on railroad tank car failure to develop risk models for different car type / use pattern scenarios.
- Conducted large ecological risk assessment studies for pesticides including the development of statistical analyses and Monte Carlo models to predict the risks that a pesticide might pose to the reproductive success of birds. Conducted analyses of data from both mesocosm and fish life cycle studies to determine the environmental risks posed by an herbicide.
- Broadly involved in development of chemical risk estimates through the analysis of rodent bioassay data.
- Modeled the risks of indoor air pollution and radiation exposure to airliner passengers, and performed probability of causation calculations in support of litigations defending alleged radiation injury.
- Provided cancer risk modeling for less-than-lifetime exposures, and probability of causation calculations in support of toxic tort litigations.
- Led risk studies of the risks of electric field exposure in office buildings, and directed two large risk assessments, one for coal gasification and the other for advanced battery technologies.
- Developed models for monitoring of nuclear power plant emissions.
- Developed models for canister failure in high level radioactive waste storage facilities.

Environmental Characterization and Monitoring

- Dr. Ginevan's book "*Statistical Tools for Environmental Quality Measurement*" deals with the statistical bases of environmental characterization studies.
- Recent projects include:
 - Statistical analysis of dioxin contamination at several former industrial sites.
 - Evaluation of chemical concentrations in dust samples from buildings adjacent to the World Trade Center (WTC) Site to determine whether or not there is a consistent chemical "signature" in this dust, evaluations of PCB and dioxin congener profile data to determine the likely source of contamination
 - A comprehensive evaluation of the National Antimicrobial Monitoring System (NARMS) designed to assess its value in critical decision making.

- Other projects:
 - Design of monitoring programs for environmental residues of pesticides.
 - Developed survey designs for pesticide residues in food products.
 - Developed statistical designs for indoor air monitoring studies.
 - Provided reviews of the adequacy of the environmental sampling programs at several hazardous waste sites, including Superfund sites.
 - Reviewed EPA guidance materials on the Data Quality Objectives / Data Quality Assessment Process (DQO/DQA).
 - Acting as a consultant to EPA's Science Advisory Board, provided reviews of the Multi-Agency Radiological Laboratory Analytical Protocols Manual (MARLAP) and the Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM).
 - Provided statistical advice to the EPA in the areas of monitoring ambient air quality and, as a member of a Science Advisory Board subcommittee, indoor radon.
 - Planned air monitoring programs to verify incinerator performance.
 - Provided statistical design for a large air quality survey for Valdez, Alaska.
 - Participated in the planning and oversight of the EPA's terrestrial biomonitoring program.

Databases and Data Quality Objectives

- Evaluated historical databases related to herbicide use, troop locations and military action during the Vietnam War and helped translate these data into a modern relational database.
- Evaluated records quality in a large asbestos exposure database to determine its usefulness in product liability litigation.
- Assisted the pesticide industry in development of a large pesticide use database and worked with the Agricultural Reentry Taskforce in developing a large database of worker exposure information.
- Played a central role in the development of the pesticide residue database used in an ecological risk assessment study, and was also responsible for the development and implementation of both analytic and graphical statistical procedures for data exploration and quality assurance. The actual database included more than 20,000 pesticide residue measurements.
- At DOE, managed development of the Comprehensive Epidemiologic Data Resource (CEDR) system from 1991 to 1993. The CEDR database system was developed by the U.S. Department of Energy (DOE) to make all of the data collected by the DOE epidemiologic studies available to the scientific community. These data include 12 distinct studies, and more than 30,000 individual records. Played a major role in defining the information necessary to make CEDR a "user friendly" system and in defining quality assurance criteria for these data. Today, CEDR is complete and is available through the Internet.
- At the U. S. Nuclear Regulatory Commission, planned development of a dosimetry database for nuclear power plant workers and developed statistical methods that might be used to better estimate worker exposure from the resulting data.

Michael Ginevan, Ph.D.

Michael E. Ginevan: Bibliography

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Chen, L., Zhao, T., Ross, J., Ginevan, M., Vega, H., Krieger, R. (2013). Absorption and excretion of organophosphorous insecticide biomarkers of malathion in the rat: Implications for overestimation bias from environmental biomonitoring. *Regul. Toxicol. Pharm.* 65, 287–293.

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Michael Ginevan, Ph.D.

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Ginevan, M.E., D.K. Watkins, J.H.Ross and R.A. O’Boyle. 2009. Assessing exposure to allied ground troops in the Vietnam War: A quantitative evaluation of the Stellman Exposure Opportunity Index model. *Chemosphere*. 75:1512–1518.

Ginevan, M.E., J.H. Ross and D.K. Watkins. 2009. Assessing exposure to allied ground troops in the Vietnam War: A comparison of AgDRIFT and Exposure Opportunity Index Models. *Journal of Exposure Science and Environmental Epidemiology*. 19:187-200.

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Michael Ginevan, Ph.D.

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Michael Ginevan, Ph.D.

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