

Abby A. Li, Ph.D.
Senior Managing Scientist

Professional Profile

Dr. Abby A. Li is a Senior Managing Scientist in Exponent's Health Sciences Center for Toxicology and Mechanistic Biology. Dr. Li has extensive experience addressing toxicology, risk assessment, and other regulatory science issues related to human and environmental exposure for a wide range of chemicals, including pesticides, industrial chemicals, medical devices, and pharmaceuticals. She also has registration and re-registration management experience for pesticides, dealing with a wide range of risk assessment issues internationally. Her particular strengths include identifying and understanding key scientific issues that affect regulatory risk assessment decisions (i.e., application of uncertainty and FQPA factors), and selecting the appropriate application of toxicology data for quantitative risk assessment approaches (i.e., benchmark dose, CxT analyses, cumulative risk assessment). She has extensive experience in product stewardship, and design, project management, and analysis of toxicology studies.

Dr. Li has served on several international and national expert panels, including those sponsored by the National Academy of Science, the Organization of Economic Cooperation and Development (OECD), and the International Life Science Institute. Dr. Li served for 6 years as a full member of the Environmental Health Committee, a committee of EPA's Science Advisory Board. She is recognized as an expert in neurotoxicology in the U.S. and internationally. She served on the United States Expert Team to develop international guidelines for neurotoxicology and developmental neurotoxicology for the OECD. She chaired the American Industrial Health Council's Neurotoxicology Subcommittee, frequently making public presentations to EPA scientific panels on scientific issues related to neurotoxicology. Dr. Li was the chair of the American Chemistry Council's Neurotoxicology Technical Panel, and she led an expert panel of industrial, government, and academic neuroscientists overseeing long-range research projects to advance the field of neurotoxicology.

Previously at Monsanto Company, Dr. Li was appointed Senior Science Fellow and provided expertise in risk assessment, toxicology, and neurotoxicology. As Neurotoxicology Team Leader at Monsanto's Environmental Health Laboratory, she developed neurotoxicology research capabilities, including schedule-controlled operant behavior, learning and memory, auditory startle habituation, functional observational battery, motor activity, developmental neurotoxicology, neuropathology, and glial fibrillary acidic protein biochemical assays. She was a study director for numerous toxicology, metabolism (ADME), and neurotoxicology studies conducted under Good Laboratory Practice. She also was study monitor for specialized studies involving *in vitro* assays, whole-animal bioassays, and human epidemiological studies. Dr. Li was also the global regulatory team leader for a multidisciplinary team of experts who were responsible for addressing a wide range of regulatory science issues, including surface water risk assessment, cancer risk assessment, neurotoxicology, ecological risk assessment.

Academic Credentials and Professional Honors

Ph.D., Pharmacology and Physiology, University of Chicago, 1985
B.A., Chemistry, University of Chicago, 1979

Outstanding published paper in 2009 demonstrating an application of risk assessment awarded by Society of Toxicology Risk Assessment Specialty section, awarded March 8, 2010. [Paper: DeSesso JM, Watson RE, Keen CL, Hazelden KP, Haws LC, Li AA. Analysis and integration of developmental neurotoxicity and ancillary data into risk assessment: A case study of dimethoate. *JTEH Part A* 2009; 94–109].

2009 Johns Hopkins University Center for Alternatives in Animal Testing Recognition Award “for providing a vision and strategy to bring toxicology into the 21st century.”

Doerenkamp-Zbinden Award for distinguished service for animal protection in Science, awarded to authors of the NAS/NRC vision report, “Toxicity Testing in the 21st Century,” at the 7th World Congress on alternatives to Animal Use in the Life Sciences in Rome, Italy, September 3, 2009

Monsanto Regulatory Award for Triallate Human Neurophysiology Study, 2002; Environmental and Public Affairs Excellence Award, Monsanto Agricultural Company, 1992; Achievement Award for outstanding leadership of the neurotoxicology team in developing new testing capabilities, Monsanto Agricultural Company, 1991; National Institute of Mental Health National Research Service Award, University of Chicago, Department of Pharmacology and Physiology, 1980–1985

Publications

Li, AA, Levine TE, Burns CJ, Anger WK. Integration of epidemiology and animal neurotoxicity data for risk assessment. *NeuroToxicology* 2012 May, in press, 2012 Feb 7. Epub ahead of print.

Llorens J, Li A, Ceccatelli S, Sunol C. Strategies and tools for preventing neurotoxicity: To test, to predict and how to do it. *NeuroToxicology* 2012 May, in press 2012 Feb 4. Epub ahead of print.

Mink PJ, Kimmel CA, Li AA. Potential effects of chlorpyrifos on fetal growth outcomes: implications for risk assessment. *JTEH Part B* 2012; 15:281–316.

Bal-Price AK, Coecke S, Costa L, Crofton KM3, Fritsche E, Goldberg A, Grandjean P, Lein PL, Li A, Lucchini R, Mundy WR, Padilla S, Persico AM, Seiler AEM, Kreysa J. Advancing the Science of developmental neurotoxicity (DNT): Testing for better safety evaluation. *ALTEX* 2012; 29:202–215.

Li, AA, Fowles J, Banton M, Picut C, Kirkpatrick D. Acute inhalation study of allyl alcohol for derivation of acute exposure guideline levels. *Inhalation Toxicology* 2012; 24:213–226.

Li, AA, Lowe, KA, McIntosh, LJ, Mink, PJ. Evaluation of epidemiology and animal data for risk assessment: Chlorpyrifos developmental neurobehavioral outcomes. *JTEH Part B* 2012; 15:109–185.

DeSesso JM, Watson RE, Keen CL, Hazelden KP, Haws LC, Li AA. Analysis and integration of developmental neurotoxicity and ancillary data into risk assessment: A case study of dimethoate. *J Toxicol Environ Health Part A* 2009; 94–109.

Li AA, Baum MJ, McIntosh LJ, Day M, Liu F, Gray LE. Building a scientific framework for studying hormonal effects on behavior and on the development of the sexually dimorphic nervous system. *Neurotoxicology* 2008; 29:504–519.

Krewski D (chair), Li AA (one of 22 authors). Toxicity testing in the 21st Century: A vision and a strategy. National Research Council of the National Academies. National Academies Press, Washington D.C., 2007. ISBN-13 978-0-309-10992-5. <http://www.nap.edu>.

Coecke S, Goldberg AM, Allen S, Buzanska L, Calamandrei G, Crofton K, Hareng L, Hartung T, Knaut H, Honegger P, Jacobs M, Lein P, Li A, Mundy W, Owen D, Schneider S, Silbergeld E, Reum T, Trnovec T, Monnet-Tschudi F, Bal-Price A. Work group report: Incorporating in vitro alternative methods for developmental neurotoxicity into international hazard and risk assessment strategies. *Environ Health Perspect* 2007 Jun; 115(6): 924-31.

Krewski D (chair), Li, AA (one of 22 authors). Toxicity testing for assessment of environmental agents. Committee on Toxicity Testing and Assessment of Environmental Agents. National Research Council of the National Academies. National Academies Press, Washington D.C., 2006. ISB# 0-309-10092-5. <http://www.nap.edu>.

Cooper RL, Lamb JC, Barlow SM, Bentley K, Brady AM, Doerrer NG, Eisenbrandt DL, Fenner-Crisp PA, Hines RN, Irvine LF, Kimmel CA, Koeter H, Li AA, Makris SL, Sheets LP, Speijers G, Whitby KE. A tiered approach to life stages testing for agricultural chemical safety assessment. *Crit Rev Toxicol* 2006; Jan; 36(1):69–98.

Li AA, Mink P, McIntosh, LJ, Teta M, Finley B. Evaluation of epidemiologic and animal data associating pesticides with Parkinson's Disease. *J Occup Environ Med* 2005; 47(10):1059–1087.

Slikker W, Acuff K, Boyes WK, Chelonis J, Crofton KM, Dearlove GE, Li A, Moser VC, Newland C, Li Rossi J, Schantz S, Sette W, Sheets L, Stanton M, Tyl S, Sobotka TJ. Behavioral test methods workshop. *Neurotoxicol Teratol* 2005; 27(3):417–427.

Li AA. Regulatory developmental neurotoxicology testing: Data evaluation for risk assessment purposes. *Environ Toxicol Pharmacol* 2005; 19(3):727–733.

Middaugh LD, Dow-Edwards D, Li AA, Sandler JD, Seed J, Sheets LP, Shuey DL, Slikker W, Weisenburger WP, Wise LD, Selwyn M. Neurobehavioral assessment: A survey of use and value in safety assessment studies. *Toxicol Sci* 2003; 76(2):250–261.

Dorman DC, Allen SL, Byczkowski JZ, Claudio L, Fischer JE, Fisher JW, Harry GJ, Li AA, Makris SL, Padilla S, Sultatos LG, Mileson BE. Methods to identify and characterize developmental neurotoxicity for human health risk assessment: III. Pharmacological considerations. *Environ Health Perspect* 2001; 109 Suppl 1:101–111.

Moser VC, Bowen SE, Li AA, Sette WS, Weisenburger WP. Cognitive evaluation: Is it needed in neurotoxicity screening? *Neurotoxicol Teratol* 2000; 22:7850–798.

Li AA, Thake DC, Kaempfe TA, Branch DK, O'Donnell P, Speck FL, Tyler TR, Faber WD, Jasti SL, Ouellette R, Banton MI. Neurotoxicity evaluation of rats after subchronic inhalation exposure to Isobutanol. *Neurotoxicol* 1999; 20(6):889–900.

Boyes WK, Dourson ML, Patterson J, Tilson HA, Sette WF, MacPhail RC, Li A, O'Donoghue JL. EPA neurotoxicity risk assessment guidelines. *Fundam Appl Toxicol* 1997; 40:175–184.

Albee R, Li A, Moser V, O'Donoghue J, Ross J, and Sheets L. U.S. EPA/AIHC training video and reference manual for a functional observational battery, 1996.

Li AA. Functional assessment: From benchtop to regulator. Proceedings, The Toxicology Forum, 1994 Annual Summer Meeting, The Given Institute of Pathobiology, 1994.

Li AA. The use (misuse) of schedule-controlled operant behavior in neurotoxicity testing. In: *Toxicological Interpretation of Neurobehavioral Data*. Weiss B and O'Donoghue J (eds), New York, Argus, 1994.

Rees DC, Li AA. Schedule-controlled operant behavior I. Identification of neurotoxicity: Critical summary of workshop discussion and implications. In: *Toxicological Interpretation of Neurobehavioral Data*. Weiss B and O'Donoghue J (eds), New York, Argus, 1994.

Marek GJ, Heffner TG, Shaughnessy RA, Li AA, Seiden LS. Effects of caffeine and PD 116,600 on the differential-reinforcement-of-low-rate 72-s (DRL 72-s) schedule of reinforcement. *Pharm Biochem Beh* 1994.

Li AA, Asbury KJ, Hopkins WE, Feng PCC, Wilson AGE. Metabolism of alachlor by rat and monkey liver nasal turbinate tissue. *Drug Metabol Disposit* 1992; 20:616–618.

Li AA, Marek GJ, Hand TH, Seiden LS. Antidepressant-like effects of trazodone on a behavioral screen are mediated by trazodone, not the metabolite m-chlorophenylpiperazine. *Eur J Pharm* 1990; 177:137–144.

Li AA, Marek GJ, Vosmer G, Seiden LS. Long-term central 5-HT depletions resulting from repeated administration of MDMA enhances the effects of single administration of MDMA on schedule-controlled behavior of rats. *Pharm Biochem Beh* 1989; 33:641–648.

Marek GJ, Li AA, Seiden LS. Evidence for involvement of 5-hydroxytryptamine₁ receptors in antidepressant-like drug effects on differential-reinforcement-of-low-rate 72-s behavior. *J Pharmacol Exp Ther* 1989; 250:60.

Marek GJ, Li A, Seiden LS. Selective 5-hydroxytryptamine₂ antagonists have antidepressant-like effects on differential -reinforcement-of-low rate 72-s schedule. *J Pharmacol Exp Ther* 1989; 250:52–59.

Seiden LS, Marek GJ, O'Donnell JM, Li A, Dunn R, Jolly D. The role of noradrenergic and serotonergic systems in the screening of antidepressant drugs. Proceedings, 6th Club CA Symposium, Jerusalem, Israel, June 1987.

Invited Lectures

Li AA (Symposium Chair and lecturer). Integration of animal data for risk assessment. International Neurotoxicology Association Biennial Meeting, Xi'an, China, June 2011.

Li AA (Invited steering committee member and lecturer). In vitro methods and risk assessment. 3rd international Conference on Developmental Neurotoxicity 3 (DNT3) organized by ECVAM, the European Centre for the Validation of Alternative Methods of JRC of the European Commission, Varese, Italy, May 2011.

Li AA (Invited Workshop Participant and Panelist). Computational toxicology: From data to analyses to applications. National Academy of Science Emerging Science for Environmental Health Decisions, Washington D.C., September 2009.
http://dels.nas.edu/envirohealth/sept_participantinfo.shtml.

Li AA, Levine T. (Session Chairs and Speakers). Pesticides and Parkinson's disease: Implications of new epidemiology and exposure data to risk assessment. Session Talk by Abby Li: Pesticide risk assessment and animal models of PD. Society of Toxicology Annual Meeting, Baltimore, MD, March 2008.

Li AA, Gray LE (Session Chairs and Speakers). Developing a framework for studying hormonal effect on sexual differentiation of the brain. International Neurotoxicology Association Meeting, Pacific Grove, CA, June 2007.

Li AA. Developmental neurotoxicology testsmart: Validation for what purpose? Center for Alternatives to Animal Testing, Reston, VA, March 2006.

Li AA. From rat to human: risk assessment for developmental neurotoxicology studies (DNT). Summer Toxicology Forum, Aspen, CO, July 2003.

Li AA, Maurissen J, Mundy W, Crofton K. Developmental neurotoxicology: data interpretation and risk assessment. International Neurotoxicology Association 9, Dresden, Germany, June 2003.
Li AA, Barnett JF, Maurissen J. Developmental neurotoxicity testing, testing and data interpretation. Invited lecturer for continuing education course on mechanisms, biomarkers, data

interpretation: An integrative risk assessment using DNT as a model. Teratology Society Meeting, Scottsdale, AZ, June 2002.

Li AA. Neurotoxicology of Triallate, a thiocarbamate. International Neurotoxicology Association Meeting, Estoril, Portugal, June 2001.

Li AA. Neurotoxicology. Invited Lecturer to American Industrial Hygiene Association Toxicology Course, Redondo Beach, CA August 2000; Williamsburg, VI, August 1999.

Li AA. The value of developmental neurotoxicology testing. Winter Toxicology Forum, Washington D.C., November 1999.

Li AA. Implications of EPA's Neurotoxicity Risk Assessment Guidelines from a FIFRA Perspective. EPA's Neurotoxicity Risk Assessment Guidelines Workshop, Society of Toxicology, March 1997.

Li AA. Industry Perspective on EPA's Proposed Neurotoxicology Risk Assessment Guidelines. Summer Toxicology Forum, Aspen, Colorado, July 10, 1996.

Li AA. Session Organizer: Neurotoxicity testing: Are we on the right track? 5th International Neurotoxicity Association Meeting, Port Ludlow, WA, June 1995.

Li AA. Neurotoxicological evaluations in adult animal studies. American College of Toxicology, 15th Annual Meeting, Williamsburg, VI, October 23, 1994.

Li AA. Functional testing: from benchtop to regulator. Annual Summer Toxicology Forum, Given Institute of Pathobiology, Aspen, CO, July 12, 1994.

Li, A.A. An industrial perspective of neurotoxicity toxicity testing. University of Washington, Department of Environmental Health School of Public Health and Community Medicine, Seattle, WA, May 19, 1994.

Li AA. FDA Redbook II: Industry's response to neurotoxicity test guidelines. Conference on the U.S. Food and Drug Administration's Redbook II, sponsored by the International Life Sciences Institute, Washington D.C., December 17, 1993.

Li AA. Neurotoxicity testing. CliniChem-93, Sponsored by the American Association for Clinical Chemistry, Albany, NY, October 15, 1993.

Li AA. Invited lecture to EPA toxicology reviewers: neurotoxicity testing: Introduction to conduct of studies and interpretation of data. Environmental Protection Agency, Crystal City, VI, April 28, 1993.

Li AA. Neurotoxicity testing. University of Washington, Department of Environmental Health School of Public Health and Community Medicine, Seattle, WA, April 8, 1993.

Li AA. Neurotoxicity screening battery. Symposium on Occupational and Environmental Neurotoxicology, Northwest Center for Occupational Health and Safety (supported by National Institute for Occupational Safety and Health), Seattle, WA, March 11, 1993.

Li AA. Neurotoxicity testing in animals. Occupational and Environmental Toxicology Symposium, sponsored by the Northwest Center for Occupational Health and Safety and University of Washington, Seattle, WA, March 11, 1993.

Li AA. The use (misuse) of schedule-controlled operant behavior in regulatory testing. 18th Rochester Conference: Toxicological Interpretation of Neurobehavioral Data, Rochester, NY, June 1992.

Li AA. Neurobehavioral testing: The good, the bad, and the ugly. Society of Toxicologic Pathologists, 11th International Symposium, Neuropathology/Neurotoxicology Workshop, Phoenix, AZ, June 5–6, 1992.

Prior Experience

Senior Science Fellow/Toxicologist and Registration Manager, Monsanto, 1989–2002

Project Experience

Conducted projects related to industrial chemicals (including trichloroethylene, xylene, ethylbenzene, alkanolamines, bisphenol A, manganese) and pesticides (including organophosphates, carbamates, neonicotinoids).

Organized expert review and presented scientific and risk assessment of toxicology data for agricultural and industrial chemicals to regulatory authorities or scientific advisory panels.

Evaluated use of toxicology data in quantitative analyses for carbamate and organophosphate risk assessments, both cumulative and individual, including EPA's use of empirical dose-time response model written in "R" based on combining adult and offspring cholinesterase inhibition data from different laboratory studies.

Conducted risk assessments and derivations of reference doses (RfDs) based on a weight-of-evidence approach to evaluating toxicology databases and quantitative benchmark dose analyses of toxicology and reproduction and developmental studies.

Designed, evaluated, and monitored U.S. and international guideline adult and developmental neurotoxicology studies, with additional components added to address specific concerns relevant to different modes of action.

Designed and monitored specialized acute inhalation study specifically to improve the scientific database for derivation of AEGL values.

Provided state-of-the-science review and assessment of developmental neurotoxicology literature for specific chemicals undergoing review by scientific expert panels (NTP CERHR, VCCEP expert committee).

Designed a study funded by competitive grant from the UK Pesticide Safety Directorate to evaluate whether human-relevant routes of exposure and dosing as a juvenile or young adult resulted in Parkinson's disease-like neurodegeneration in mice.

Conducted and published literature review of the epidemiology and animal studies on the association between pesticides and Parkinson's disease.

Academic Appointments

- Assistant Professor (Adjunct), St. Louis University, School of Public Health, 1994–1999
- Visiting Scholar, University of Washington, Department of Environmental Health, School of Public Health and Community Medicine, Seattle, Washington, 1993
- Assistant Professor (Adjunct), Department of Natural Sciences, Fontbonne College, St. Louis, Missouri, 1988–1989

Research Experience

Dr. Li was the Primary Investigator (Study Director) and/or Technical Lead (Senior Author) for over 30 scientific reports for studies conducted according to Good Laboratory Practices to support registration of chemicals. These include EPA guideline studies, as well as more advanced mechanistic studies. Documentation of many of these reports (e.g., title, author) can be found on the National Pesticide Information Retrieval Service (NPIRS).

Consulting and Advisory Appointments

- Chair, American Chemistry Council Neurotoxicology Technical Panel. Scientific lead for an expert panel of industrial, government and academic neuroscientists in allocation of research dollars to advance the field of neurotoxicology, 2000–2002.
- Technical Leader – American Crop Protection Agency Developmental Neurotoxicology Task Force. Led technical discussions between ACPA and EPA on design of Developmental Neurotoxicity studies, Washington DC, 2000.
- Chair – American Industrial Health Council Neurotoxicology Subcommittee, Washington D.C.: Chaired subcommittee of neurotoxicology experts from industry that initiated activities to advance the state of the science related to neurotoxicology testing and risk assessment. Served as spokesperson for industry in scientific issues related to neurotoxicology, 1993–1998.
- CMA Neurotoxicity Technical Task Force. Key scientist developing protocol design for schedule-controlled operant behavior and neurotoxicity studies to satisfy Multisubstance Test Rule, 1993–1995.

Science Advisory Boards/Panels

- Member, U.S. EPA's Science Advisory Board Risk and Technology Review Panel. The panel is conducting a peer review of EPA's draft health and environmental assessments of industrial emissions of hazardous air pollutants, 2009–present
- Chair, Developmental Neurotoxicology Work Group, Crop Life America. Committee focused on improving the scientific and experimental basis for regulatory decision making with respect to evaluating potential effects of chemicals/pesticides on the developing nervous system. Committee is made up of toxicologists from member companies who have conducted and/or analyzed developmental neurotoxicology studies, 2008–present
- Johns Hopkins Bloomberg School of Public Health Center for Alternatives in Animal Testing DNT TestSmart 2, Steering Committee Member and Faculty. Committee member organizing workshop conference evaluating the use of high throughput in vitro methods for developmental neurotoxicity testing, 2007–2008
- National Academy of Science National Research Council Committee on Toxicity Testing and Assessment of Environmental Agents. Publication of “Toxicity testing in the 21st Century: A vision and a strategy.” Committee member preparing 2-volume report on using emerging science and tools (e.g. genomics, proteomics, transgenics; pharmacokinetics, mechanisms of action) into human health risk assessment.,2004–2007
- National Academy of Science (NAS) National Research Council Committee on Toxicity Testing and Assessment of Environmental Agents. This committee was charged with evaluating the use of emerging science and tools of toxicology testing for regulatory purposes, and this work was summarized in an NAS publication titled, Toxicity Testing in the 21st Century: A vision and a strategy, 2004–2005
- ILSI Agricultural Chemical Safety Assessment Life-Stages Committee. Member of committee evaluating safety assessment testing for different life stages (fetus, infant, elderly) and developing new strategies for testing pesticides, 2002–2004
- EPA Science Advisory Board Environmental Health Committee, full member for three 2-year terms. EPA's SAB is composed of non-federal government scientists who provide independent advice directly to the EPA administrator on technical aspects of public health and environmental issues, 1996–2002
- Peer consultant, EPA Benchmark Dose Peer Consultation Workshop. September 10–11, 1996
- United States Expert Delegate – OECD Neurotoxicity and Developmental Neurotoxicity Expert Workgroup. Invited by EPA to serve on U.S. team of experts to develop international OECD guidelines on neurotoxicity, 1995–1998, and developmental neurotoxicity, 1996–2000

Editorships and Editorial Review Boards

- Editorial Board, *NeuroToxicology*, Intox Press, Inc., 1995–2002

Peer Reviewer

- *NeuroToxicology*, 2004–2005; 2008

Professional Affiliations

- Society of Toxicology
- International Neurotoxicology Association (Scientific Committee for INA-9, 2003)
- Neurobehavioral Teratology Society