

Karyn L. Hentz, MSPH, RAC, DABT
Managing Scientist

Professional Profile

Ms. Karyn L. Hentz is a Managing Scientist in Exponent's Health Sciences Center for Toxicology and Mechanistic Biology. Ms. Hentz is a board-certified toxicologist with over 20 years of experience in litigation support, regulatory support, exposure, and risk assessment, involving a broad range of industrial chemicals, crop protection chemicals, personal care products, pharmaceuticals, medical devices, and foods. Ms. Hentz is also Regulatory Affairs Certified (RAC) in U.S. FDA regulations and provides regulatory support for a range of healthcare products including drugs and medical devices.

She has been involved in developing scientific strategy, conducting critical reviews of the literature for causation analyses, and assessing potential exposure of plaintiffs for both individual claims and large toxic tort cases. She has provided expert witness support, identified areas for potential cross-examination, assisted in the preparation of pre-trial motions, and prepared demonstratives for trial. Her experience in litigation cases has involved exposure to solvents, metals, dioxins, PCBs, and pesticides.

Ms. Hentz has assisted in the registration of products with FDA, EPA, and the EMEA. She has provided toxicological analysis and support for drug substances and excipients, food additives, crop-protection compounds, and medical devices. She has participated in study monitoring of toxicological studies for pre-clinical testing requirements of pharmaceuticals and medical devices. She has provided regulatory support for products post-market through preparation of comments and risk assessments for submission to regulatory agencies.

She has conducted quantitative risk and exposure assessments for Superfund sites, California Prop 65, excipients in drug products, and accidental exposures. She has performed Monte Carlo analyses, as well as site- or product-specific analyses, in order to more realistically characterize exposure and risk. Recently, she was involved in the development of a tolerable daily intake for a drug product using the benchmark dose approach that was first approved by the EMEA using this approach.

Academic Credentials and Professional Honors

M.S., Public Health, Environmental Sciences, The University of Hawaii, 1990
B.A., Biology, Gettysburg College, 1983

Licenses and Certifications

American Board of Toxicology, Diplomate, 2002–present
Regulatory Affairs Certified (RAC)

Publications

Lamb J, Hentz K, Schmitt D, Tran N, Jonker D, Junker K. A one-year oral toxicity study of sodium stearoyl lactylate (SSL) in rats. *Food Chem Toxicol* 2011; 48: 2663–2669.

Nichols BR, Hentz KL, Aylward L, Hays SM, Lamb JC. Age-specific reference ranges for polychlorinated biphenyls (PCB) based on the NHANES 2001–2002 Survey. *J Toxicol Environ Health A* 2007; 70(21):1873–1877.

Lamb JC IV, Hentz KL. Toxicological review of male reproductive effects and trichloroethylene exposure: Assessing the relevance to human male reproductive health. *Reprod Toxicol* 2006; 22(4):557–563.

Hentz KL, Pirages SW, Williams KA. Differences in indirect risk methodologies: Dioxin emission from combustion facilities. *Regul Toxicol Pharmacol* 1994; 20:83–95.

Simmonds JS, Washburn S, Hentz KL, Harris R. Developments in the use of risk assessments to evaluate complex hazardous waste management facilities. *Environmental Professional*, December 1992.

Abstracts/Presentations

Hentz KL, Lamb JC. Proposed mechanism of action for toxicity in N-acetylcysteine overdose. Poster presented at Society of Toxicology Annual Meeting, 2011.

Tsuji J, Hentz K, Rosenbloom S, Bogen K, Yost L. Health risk of internal nickel exposure from medical devices. Poster presented at Society of Toxicology Annual Meeting, 2010.

Hentz KL, Neal BH, Tyl RW, Hoberman AM, Wilson D. Sporadic occurrence of low fertility rates in control CD rats. *Int J Toxicol* 2010; 29(1):95. Presented at the American College of Toxicology Annual Meeting, 2009.

Lamb J, Ryan B, Gaylor D, Hentz K, Gerhart J. Derivation of an acceptable daily intake (ADI) using a benchmark dose (BMD) approach for a veterinary pharmaceutical residue in food-producing animals. Poster presented at American College of Toxicology Annual Meeting, 2008.

Hentz KL, Karch NJ, Ginevan ME. Statistical analysis of binned data without access to raw data. Presentation at Annual SRA Meeting, Baltimore, MD, 2003.

Hentz KL, Oredugba BO, Lamb JC. A review of the epidemiological evidence for risk of breast cancer associated with exposure to polychlorinated biphenyls (PCBs). *Int J Toxicol* 2002; 21(6):526–527. Presented at the American College of Toxicology Meeting, 2002.

Karch NK, Soto AN, Norenberg KM, Hentz KL. Review of changes in LTP and behavioral/learning effects in rats treated with PCBs. Poster presented at Society of Toxicology Annual Meeting, 2002.

Norenberg KM, Hentz KL, Neal BH, Lamb JC. Evaluation of a common mechanism for dithiocarbamates. *Toxicologist* 2002; 66:175. Poster presentation at Society of Toxicology Annual Meeting, 2002.

Oredugba BO, Hentz KL, Lamb JC. Review of toxicity data and assessment of the margin of exposure for di-butylphthalate (DBP) as an inert ingredient in a generic drug. *Toxicologist* 2002; 66. Poster presented at Society of Toxicology Annual Meeting, 2002.

Soto AN, Hentz KL, McCarty JD, Lamb JC. Evaluation of the estrogenic activity of pyrethroid pesticides. *Toxicologist* 2002; 66. Poster presented at Society of Toxicology Annual Meeting, 2002.

Hentz KL. Biostatistics and Epidemiology: Study design in medical research. Guest lecturer at Georgetown University, Division of Biostatistics and Epidemiology, School of Medicine, May 11, 1999.

Hentz KL. Quantitative approaches in risk assessment. Half day continuing education seminar presented at the Professional Conference of Industrial Hygiene sponsored by the American Industrial Hygiene Association, 1998.

Rodan BD, Arfsten DP, Karch NJ, Hentz KL. Revisiting the urban factor in air pollution mortality studies. In: *Decision Making in Public Health: Priorities, Power, and Ethics*. American Public Health Association 123rd Annual Meeting & Exhibition, San Diego, CA, October/November 1995.

Hentz KL. Advanced topics in risk assessment. Day-long continuing education seminar presented at the Professional Conference of Industrial Hygiene sponsored by the American Industrial Hygiene Association, 1995, 1996, 1997 and 1998.

Hentz KL, Williams KA, Karch NJ. A comparative exposure assessment of EPA indirect guidance on dioxin using point estimates and Monte Carlo techniques. Presented at the Society for Risk Analysis Annual Meeting, December 4–7, 1994.

Hentz KL, Rosolowsky LJ, Li WW, Lage G. Case-study comparison of reasonable worst-case and Monte Carlo simulation approaches to risk assessment. Poster presentation at Society of Toxicology Annual Meeting, March 14–18, 1993.

Rosolowsky LJ, Hentz KL, Perkins BK, Shimada B. A baseline risk assessment of a Superfund site involving exposure to seeps of tar-like material. Poster presentation at Society of Toxicology Annual Meeting, March 14–18, 1993.

Book Chapters

Lamb JL, Hentz KL. Chapter 3. Impact of endocrine disruptor policies and regulations. In: Endocrine Toxicology, Volume 27 in: Target Organ Toxicology. Eldridge, JS, Stevens JT (eds), New York: Informa Healthcare, 2010.

Hentz KL. Chapter 3.03, Safety assessment of pharmaceuticals. Comprehensive Toxicology, Second Edition. Volume 3: Toxicology Testing and Evaluation. Lamb JC (ed), Elsevier: Oxford, 2010.

Prior Experience

Senior Consultant, The Weinberg Group Inc., 2003–2009

Senior Scientist/Manager, Blasland, Bouck, and Lee (BBL), 1999–2003

Senior Staff Scientist, Karch & Associates, Inc., 1994–1999

Staff Associate, Karch & Associates, Inc., 1993–1994

Senior Associate Health Scientist, ENVIRON Corporation, 1993

Associate Health Scientist, ENVIRON Corporation, 1990–1993

Consultant, Hawaii State Department of Health, 1990

Research Assistant, ENVIRON Corporation, 1987–1988

Professional Affiliations

- American College of Toxicology, 2008–present
- Society for Risk Analysis, member, 1994–present
- Society of Toxicology, member, 1992–present