

Donna A. McMillan, Ph.D., DABT

SENIOR CONSULTANT

CONTACT INFORMATION

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PROFESSIONAL PROFILE

Dr. Donna McMillan is a Senior Consultant with ToxStrategies. She is a board-certified toxicologist with more than 30 years of experience assessing the safety of OTC drugs, cosmetics, and consumer personal care products. A member of ToxStrategies' Foods and Consumer Products group, Dr. McMillan has broad experience in the private sector, supporting product safety evaluations and development of global safety strategies for consumer products. Her work involves studying novel ingredients and new product categories for oral care, hair care, grooming, and use of botanicals and other natural substances in consumer products.

For a global consumer product developer/manufacturer, Dr. McMillan led a team of experts on human safety to develop an overall strategy for the safety assessment of botanical and natural substances (BNS) in consumer products, including dietary supplements. Her team established current best approaches for varying exposure levels to all the company's consumer products, as well as guidance for Type 1 and Type 4 Allergy assessments.

Among her industry roles, Dr. McMillan led the product safety PhD recruiting team, served on a human exposure expert team, and sat on the company's corporate Institutional Review Board. She has published widely in the scientific literature since 1984, and regularly presents at professional conferences.

EDUCATION AND DEGREES EARNED

1986–1988	Postdoctoral work, Department of Pharmacology & Toxicology, University of Arizona, Tucson
1986	Ph.D. in Pharmaceutical Sciences, University of Nebraska Medical Center, Omaha
1983	M.S. in Pharmacodynamics & Toxicology, University of Nebraska Medical Center, Omaha
1980	B.S. in Microbiology (Chemistry minor), University of Central Florida, Orlando

PROFESSIONAL ACTIVITIES

- 2012–present Member, American Society of Pharmacognosy
- 1990–present Member and Diplomate of the American Board of Toxicology (DABT)
- 1986–present Member, Society of Toxicology

SELECTED PROFESSIONAL EXPERIENCE

Health Care Products

Designed and implemented US FDA Investigational New Drug (IND) pre-clinical safety programs (up to the carcinogenicity studies when the programs were stopped by R&D) for two novel oral care active ingredients with reactive chemistry.

Designed pre-clinical and clinical safety program for a novel oral care product form for tooth whitening. Two dossiers on this technology were prepared and submitted to the EU SCCS. A similar dossier was prepared, submitted, and discussed with Health Canada and China regulatory authorities.

Regularly reviewed safety data and set safe exposure levels for flavors (natural and synthetic) in oral care and OTC health care products.

Responsible for new ingredient safety review and pre-clinical safety programs, as well as design of formulation clinical safety programs for dentifrice (North America and China), cosmetic mouth rinses (North America), denture adhesives (North America), and manual toothbrushes (North America and China).

Beauty Care Products

Provided human safety support for experimental R&D hair care projects. Work involved safety assessment of novel ingredients intended for either rinse-off or leave-on hair care treatments. Provided safety support for new clinical testing methods for efficacy.

Evaluated formulas and finished product safety testing for potential beauty product portfolio acquisitions.

Provided global human safety support for marketed and experimental manual blades and razors and shave care products.

Botanical and Natural Substance Safety

Led a global human safety expert team to develop an overall strategy for the safety assessment of botanical and natural substances (BNS) in consumer products, including dietary supplements.

Led team that established a botanical threshold of toxicological concern (TTC) (see Mahony et al., 2020).

Set standards for determining a history of safe human exposure via food/food additive exposure, and of use as a traditional herbal medicine (manuscript in preparation). Created supporting tools for daily food consumption of fruits, vegetables, and nuts (based on US and European consumption studies) and a database of the chemical constituents of common fruits and vegetables, based on published data.

Created an *in-silico* approach to safety of BNS using chemical constituent level characterization (Little et al., 2017; Roe et al., 2018).

Designed a current best approach for Type 1 allergy assessment based on protein content (Troyano et al., 2011) and for assessing the Type 4 allergy potential of BNS.

BOOK CHAPTER

Troyano E, **McMillan D**, Sarlo K, Li L, Wimalasena R. 2011. Approach to assessing consumer safety of botanical ingredients with emphasis to type 1 allergy. In: Dayan N, Kromidas L (eds), *Formulating, Packaging, and Marketing of Natural Cosmetic Products*, 1st Ed. John Wiley & Sons, Hoboken, NJ, USA, doi: 10.1002/9781118056806.ch9.

MANUSCRIPTS

Mahony CA, Bowtell P, Huber M, Kosemund K, Pfuhrer S, Zhu T, Barlow S, **McMillan DA**. 2020. Threshold of toxicological concern (TTC) for botanicals — Concentration data analysis of potentially genotoxic constituents to substantiate and extend the TTC approach to botanicals. *Food Chem Toxicol* 138:111182.

Roe AL, **McMillan DA**, Mahony C. 2018. A tiered approach for the evaluation of the safety of botanicals used as dietary supplements: An industry strategy. *Clin Pharmacol Therapeut* 104(3):446–457.

Strittholt CA, **McMillan DA**, He T, Baker RA, Barker ML. 2016. A randomized clinical study to assess ingestion of dentifrice by children. *Regul Toxicol Pharmacol* 75:66–71.

Gerlach RW, Barker ML, Sagel PA, Ralston CS, **McMillan DA**. 2008. In-use peroxide kinetics of 10% hydrogen peroxide whitening strips. *J Clin Dent* 19(2):59-63.

Mahony C, Felter SP, **McMillan DA**. 2006. An exposure-based risk assessment approach to confirm the safety of hydrogen peroxide for use in home tooth bleaching. *Regul Toxicol Pharmacol* 44:75–82.

Gerlach RW, Barker ML, **McMillan DA**, Sagel PA, Walden GL. 2004. In-use comparative kinetics of professional whitening strips: Peroxide recovery from strips, teeth, gingiva and saliva. *Comp Cont Educ Dent* 25(Suppl. 2):14–20.

Sagel PA, Odioso LL, **McMillan DA**, Gerlach RW. 2000. Vital tooth whitening with a novel hydrogen peroxide strip system: Design, kinetics, and clinical response. *Comp Cont Educ Dent* 21(Suppl. 29):10–15.

Steup DR, Hall P, **McMillan DA**, Sipes IG. 1993. Time course of hepatic injury and recovery following coadministration of carbon tetrachloride and trichloroethylene in Fischer-344 rats. *Toxicol Pathol* 21:327–334.

Steup DR, Wiersma D, **McMillan DA**, Sipes IG. 1991. Pretreatment with drinking water solutions containing trichloroethylene or chloroform enhances the hepatotoxicity of carbon tetrachloride in Fischer 344 rats. *Fund Appl Toxicol* 16:798–809.

Sipes IG, **McMillan DA**, Steup DR, Eskelson C. 1991. Synergistic hepatotoxicity in Fischer 344 rats: Effects of trichloroethylene on carbon tetrachloride metabolism and lipid peroxidation. *Proc Fourth Int Conf on the Combined Effects of Environmental Factors*. Arch Complex Environ Studies, Baltimore, MD.

McMillan DA, Schnell RC. 1985. Amelioration of bromobenzene hepatotoxicity in the male rat by zinc. *Fund Appl Toxicol* 5:297–304.

Schnell RC, **McMillan DA**, Merrick BA, Davies MH. 1984. Amelioration of bromobenzene toxicity by selenium and zinc. *Trace Subst Environ Health* 18:107–123.

Schnell RC, Bozigian HP, Davies MH, **McMillan DA**, Merrick BA, Johnson KL. 1984. Circadian rhythms in acetaminophen lethality. Ninth Annual Clinical Pharmacy Symposium, Chronopharmacokinetic Drugs and Mechanisms Used to Phase Shift Circadian Patterns. Florida A&M University.

Schnell RC, Bozigian HP, Davies MH, Merrick BA, Park KS, **McMillan DA**. 1984. Factors influencing circadian rhythms in acetaminophen lethality. *Pharmacology* 29:149–157.

Hasegawa R, St John MK, Cano M, Issenburg P, Klein DA, Walker BA, Jones JW, Schnell RC, Merrick BA, Davies MH, **McMillan DA**, Cohen SM. 1984. Bladder freeze ulceration and sodium saccharin feeding in the rat,

examination for urinary nitrosamines, mutagens, and bacteria, and effects on hepatic microsomal enzymes. *Food Chem Toxicol* 22:935–942.

POSTERS, ABSTRACTS, AND PRESENTATIONS

Brown L, **McMillan DA**, Urban JD, Mihalchik AL. A tiered approach for assessing the safety of polymeric ingredients in cosmetics and personal care products. Poster presented at Society of Toxicology Annual Meeting, Nashville, TN, March 2023.

McMillan DA. Large scale botanical and phytochemical data to assist in rapid analysis for safety assessment. 18th Annual Oxford International Conference on the Science of Botanicals, Oxford, MS, April 2018.

McMillan DA, Kosemund K, Mahony C, Huber M, Bowtell P. Threshold of toxicological concern (TTC) for botanicals—Data analysis to substantiate and extend the TTC approach to botanicals. In: *The Toxicologist: Suppl to Toxicol Sci* 156(1), Abstract no. 1831, Society of Toxicology, 2017.

McMillan DA. Safety of botanical/natural substances in cosmetic products — An industry perspective. 15th Annual Oxford International Conference on the Science of Botanicals, Oxford, MS, April 2015.

Strittholt CA, Schowanek D, Barker ML, **McMillan DA**. Deterministic and probabilistic exposure modeling of data generated from a randomized clinical study investigating dentifrice ingestion in children. International Society of Exposure Science (ISES) meeting, Cincinnati, OH, October 2014.

Regg BT, **McMillan DA**, Mahony C, Laufersweiler MC, Baker TR. 2011. Development of UHPLC/UV/CAD/Q-ToF-MS/MS methodology to characterize complex botanical mixtures. Presented at the American Society for Mass Spectroscopy, 2011.

Booker DL, Bowman LA, Fiedler SK, **McMillan DA**, Barker ML, Farrell S. 12-Month clinical safety of 6% hydrogen peroxide strips used daily. *J Dent Res* 86 (Abstract 2668), 2007.

Robison SH, Greggs W, Hochwalt AE, Kohrman K, Kosemund K, **McMillan DA**, Naciff JN. Diethyl phthalate — Biomonitoring based risk assessment. *Toxicologist* 90:257 (Abstract 1260), 2006.

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McMillan DA, Bertram TA, Markiewicz VR, Machotka SU, Cifone MA. NaCl-induced cellular proliferation in rat stomach. *Toxicologist* 12:268, 1992.

McMillan DA, Lucas JB, Stotts J. Lack of IgE antibody to chlorhexidine in exposed populations. *Toxicologist* 10:220, 1990.

McMillan DA., Tokars M, Eskelson C, Sipes IG. The synergistic hepatotoxicity of carbon tetrachloride and trichloroethylene in male Fischer-344 rats. *Toxicologist* 8:95, 1988.

McMillan DA, Sipes IG. A comparison of argininosuccinic acid lyase to other indices of carbon tetrachloride-induced hepatotoxicity. *Toxicologist* 7:268, 1987.

McMillan DA, Schnell RC. Subchronic toxicity studies of cis and trans dichloroethylene in rats. *Toxicologist* 314, 1986.

Pour A, **McMillan DA**, Schnell RC. Amelioration of acetaminophen toxicity in male rats by zinc. *Toxicologist* 5:154, 1985.

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