



## **Melinda T. Donnell (Hoang), MPH**

Health Scientist

### **Summary of Experience**

Ms. Melinda Donnell is a toxicologist with 7 years of experience in the toxicology, exposure, and risk assessment of chemicals of concern in various foods and consumer products, including electronic nicotine delivery systems (ENDS) and household and personal care products. She earned a BSc in Public Health Sciences, a BA in Public Health Policy, and an MPH in Environmental Health Sciences & Policy. She has experience in quantitative exposure and risk assessments of airborne compounds in occupational and residential settings, as well as in safety evaluation of contaminants associated with foods and consumer products. Her experience includes investigating the health effects of exposure to a variety of compounds, including asbestos, per- and polyfluoroalkyl substances (PFAS), glyphosate, nitrosamines, furfuryl alcohol, titanium dioxide, and benzene. Ms. Donnell has published over 35 abstracts and peer-reviewed papers on various consumer and environmental exposure, toxicology, and risk-related topics.

### **Education**

Bachelor of Sciences (B.Sc.), Public Health Sciences, 2014, University of California, Irvine

Bachelor of Arts (B.A.), Public Health Policy, 2014, University of California, Irvine

Master of Public Health (M.P.H.), Environmental Health Sciences & Policy, 2017, George Washington University

### **Project Experience**

#### **Medical Device and Consumer Product Safety**

Conducted a safety evaluation of the use of ectoine in a personal lubricant product.

Evaluated the potential risk of exposure to trace levels of benzene in spray sunscreen products.

Evaluated the potential skin sensitization potential of metals in cosmetic tattoos.

Contributed to an exposure assessment of PFAS from the consumer use of leave-in dental products, such as mouthguards and teeth whitening trays.

Evaluated the potential inhalation and dermal exposures to consumers to phthalates from the use of fabric face masks to mitigate the spread of COVID-19.

Contributed to the development of a dermal exposure model to evaluate the potential risk associated with exposure to 4-aminobiphenyl in hair dyes.

Conducted a safety assessment involving an evaluation of the potential adverse health effects associated with consumer and occupational exposure to PFAS in fast food packaging.

Lead and performed comprehensive toxicological reviews of ingredients and harmful and potentially harmful constituents (HPHCs) of e-cigarettes and oral nicotine products in preparation of premarket tobacco application (PMTA) submissions to the U.S. Food and Drug Administration (FDA).

Contributed to the multi-disciplinary evaluation of oral nicotine pouch products in preparation of PMTA submissions, including product physicochemistry and toxicology, toxicology studies, and human health risk assessments.

Contributed to the development of a screening-level safety assessment methodology of 30 ingredients in hair cleansing conditioner products.

### **Litigation Support**

Managed and provided litigation support to testifying expert witnesses on cases related to alleged exposures to asbestos from automotive friction products, insulation, gaskets and packing, electrical products, phenolic molding components, joint compound, stucco, and talc. Reviewed and interpreted relevant asbestos literature and case-specific materials for use in the preparation of expert reports and testimony. Performed comprehensive reviews and summaries of relevant plaintiff and expert testimony and other applicable case materials.

Provided litigation support for expert witness testimony related to the human health effects of HPHCs and flavoring ingredients from the use of ENDS.

Provided litigation support for expert witness testimony related to the human health effects associated with the disposal of crude 4-methylcyclohexanemethanol in a waterway near a residential farm.

Conducted a comprehensive literature review of the potential indoor and outdoor concentrations of contaminants of potential concern resulting from a refinery fire, including particulate matter, formaldehyde, volatile organic compounds, carbonyls, and hydrocarbons.

Provided litigation support for expert witness testimony related to alleged exposures to diacetyl, 2,3-pentanedione, and 2,3-hexanedione used in microwave popcorn production and food flavoring manufacturing facilities.

### **Food Safety and Regulation**

Contributed to the development of regulatory strategies for food, beverage, and dietary ingredients through research, review, and application of U.S. and international regulatory policy.

Contributed to the preparation of safety dossiers and regulatory submission packages, including FDA GRAS Notifications, Food Contact Notifications, and New Dietary Ingredient Notifications, of various food and beverage ingredients.

Prepared and reviewed toxicological profiles on the hepatotoxicity of the ingredients in an herbal supplement, including barberry root bark powder, burdock root powder, dandelion root raw powder, ginger root, licorice root powder, marshmallow root powder, rhubarb root powder, and yellow dock root powder.

Evaluated the potential release of chemicals from polyethylene terephthalate (PET) and recycled PET bottles into beverages.

Conducted a human health risk assessment to quantify the potential human health risks associated with exposure to milk contamination in ice cream products labeled as “non-dairy”, “vegan”, and “dairy-free”.

### **Pharmaceutical Risk Assessment**

Developed health-based risk assessments describing the known and potential effects of active pharmaceutical ingredients (APIs), non-APIs, and formulated drug products. These types of assessments included permissible daily exposures (PDEs) and occupational health categorizations (OHCs) in accordance with ICH guidelines and industry standards.

Evaluated and critiqued the FDA's derivation of an acceptable intake (AI) of *N*-nitrosodimethylamine (NDMA) impurities in pharmaceutical products.

Contributed to the risk characterization of NDMA impurities in pharmaceutical products.

### **Environmental Risk Assessment**

Contributed to an evaluation of the ecological implications of PFAS from the consumer use and disposal of leave-in dental products, such as mouthguards and teeth whitening trays.

Evaluated a high-throughput screening-level method to predict the aquatic toxicity and environmental concentrations of PFAS, using the well-studied PFOA and PFOS to validate the approach.

Provided quality assurance oversight for ecotoxicology, environmental fate, physicochemical properties, product chemistry, and analytical method validation studies from protocol development through final reporting.

### **Proposition 65 Risk Assessments**

Evaluated consumer exposures and potential health risk associated with wood dust contained within a pet litter product.

Derived a No Significant Risk Level (NSRL) for furfuryl alcohol using benchmark dose (BMD) modeling.

### **Quantitative Exposure Reconstruction**

Contributed to the design and implementation of an exposure simulation study that evaluated the airborne concentrations associated with the use of pine wood- and corn-based dust produced in pet litter to adhere to Proposition 65 regulations.

Performed quantitative exposure assessments associated with the use of asbestos-containing electrical products and phenolic molding compounds to workers, bystanders, and potential take-home exposures.

### **Occupational Health**

Performed a literature review to compare the toxicity and risks of a new and old chemical formulation of turbo oil to determine which formulation was safer for pilots and flight attendants when released into cabin air.

### **State-of-the-Science Analysis**

Performed a state-of-the-science review on the potential health hazards from exposure to methylglyoxal.

### **Other Toxicological Research**

Evaluated the differences in potencies of the three asbestos fiber types (chrysotile, amosite, and crocidolite) and provided support in deriving a dose-response curve for each fiber type.

Performed a systematic review regarding the effect of anatase titanium dioxide nanoparticles on oxidative stress in mice brain.

Evaluated the Environmental Protection Agency's (EPA's) use of the database uncertainty factor and how it corresponded to their judgment of the quality of the data underlying an assessment in the IRIS file for a chemical.

Evaluated the health hazards and risks associated with engineered nanomaterials for the National Institute for Occupational Safety and Health (NIOSH).

### **Professional Experience**

#### **Health Scientist, Valeo Sciences LLC, Aug 2023 – present.**

Evaluate the toxicology, health, and safety of chemical hazards in occupational, consumer, and environmental exposure settings.

#### **Senior Consultant, Trinity Consultants – SafeBridge® Regulatory & Life Sciences Group, Jan 2023 – Aug 2023.**

Provided consulting services specializing in toxicology and human health risk assessments issues associated with the safety of ingredients in foods, beverages, and pharmaceuticals.

#### **Toxicologist, Paustenbach & Associates. Jul 2021 – Dec 2022.**

Provided consulting services involving human health risk assessment and toxicology involving issues associated with the health effects of exposure to a variety of compounds, including asbestos, benzene, crude 4-methylcyclohexanemethanol, perfluorooctanoic acid, tricresyl phosphate, and tertbutylphenyl diphenyl phosphate.

#### **Senior Associate Health Scientist, Cardno ChemRisk, Jul 2017 – Jul 2021.**

Provided consulting services involving human health risk assessment, toxicology, and quantitative exposure reconstruction involving issues associated with the health effects of exposure to a variety of compounds in occupational, residential, and consumer product settings, including asbestos, talc, diacetyl, 2,3-pentanedione, 2,3-hexanedione, phthalates, per- and polyfluoroalkyl substances, and heavy metals.

#### **Environmental and Health Sciences Intern, ICF, Oct 2016 – May 2017.**

Conducted toxicological research involving the first 10 chemicals on the EPA TSCA list.

#### **Toxicological Graduate Research Assistant, George M. Gray, Ph.D., George Washington University, Apr 2016 – Dec 2016.**

Evaluated the EPA's use of the database uncertainty factor and how it corresponded to their judgment of the quality of the data underlying an assessment in the IRIS file for a chemical.

**Student Trainee Biological Sciences (GS-05), Consumer Product Safety Commission (CPSC), Division of Toxicology and Risk Assessment, May 2016 – Aug 2016.**

Compared the Federal Hazardous Substances Act and other CPSC regulations to the Globally Harmonized System revisions 3 and 6 for classification and labeling to identify any necessary changes to be made to CPSC statutes.

**Toxicology Research Assistant, Advanced Technologies & Laboratory International, Inc., Mar 2016 – May 2016.**

Researched toxicological studies to evaluate the hazards and risks associated with engineered nanomaterials for NIOSH.

### **Certifications**

- Hazard Analysis & Critical Control Point (HACCP), 2021
- FSPCA Preventive Controls for Human Food (PCQI), 2021

### **Professional Membership and Service**

- Society of Toxicology (SOT), Full Member
  - Member of Risk Assessment, Exposure, Food Safety, and Sustainable Chemicals Specialty Sections and Southern California Regional Chapter
- Society of Risk Analysis (SRA)
  - Member of Applied Risk Management, Decision Analysis and Risk, Dose Response, Exposure Assessment, Foundational Issues in Risk Analysis, Microbial Risk Analysis, and Occupational Health and Safety Specialty Groups

### **Peer-Reviewed Publications**

Madl, A.K., M.T. Donnell, and L.T. Covell. 2024. Synthetic vitreous fibers (SVFs): adverse outcome pathways (AOPs) and considerations for next generation new approach methods (NAMs). *Crit Rev Toxicol* 1-51. DOI:10.1080/10408444.2024.2390020.

Paustenbach, D.J., S.E. Brown, J.J. Heywood, M.T. Donnell, and D.L. Eaton. 2024. Risk characterization of N-nitrosodimethylamine in pharmaceuticals. *Food Chem Toxicol* 186:114498.

Massarsky, A., J.A. Parker, L. Gloekler, M.T. Donnell, N.R. Binczewski, J.S. Kozal, T. McKnight, A. Patterson, and M.L. Kreider. 2024. Assessing potential human health and ecological implications of PFAS from leave-in dental products. *Toxicol Ind Health* 40(3):91-103.

Steimel, K.G, R. Hwang, D. Dinh, M.T. Donnell, S. More, and E. Fung. 2022. Evaluation of chemicals leached from PET and recycled PET containers into beverages. *Rev Environ Health* 39(2):251-260. DOI: 10.1515/reveh-2022-0183

Massarsky, A., M.T. Donnell, E. de Gandiaga, J.S. Kozal, L. Garnick, J.A. Kubitz, S.M. Bartell, and A.D. Monnot. 2022. Critical evaluation of ECOSAR and E-FAST platforms to predict ecological risks of PFAS. *Environ Adv* 8:100221.

Massarsky, A., M.T. Donnell, N.R. Binczewski, K. Chan, D. Dinh, J.L. Bare, and K.M. Unice. 2022. Methodology for exposure and health risk screening of phthalates potentially present in fabric face coverings. *Hum Ecol Risk Assess* 28(1):184-204.

- Massarsky, A., J.A. Parker, M.T. Donnell, E.S. Fung, and K.M. Unice. 2022. Critical evaluation of ToxCast-Reactome predicted toxicity pathway correspondence of the human liver HepG2 activity profile with observed PFOA and PFOS hazards. *Comput Toxicol* 21:100212.
- Yang, L.G., R.K. Brewster, M.T. Donnell, and R.N. Hirani. 2022. Risk characterisation of milk protein contamination in milk-alternative ice cream products sold as frozen desserts in the United States. *Food Addit Contam Part A Chem Anal Control Expo Risk Assess* 39(1):1-13.
- Fung, E.S., D.A. Drechsel, K.M. Towle, M.T. Hoang, R.M. Novick, C. Poteete, D.J. Paustenbach, and A.D. Monnot. 2018. Screening-level safety assessment of personal care product constituents using publicly available data. *Cosmetics* 5(2):38.
- Wright, D., M. Hoang, A. Sofine, J.P. Silva, and R. Schwarzkopf. 2017. Pain catastrophizing as a predictor for postoperative pain and opiate consumption in total joint arthroplasty patients. *Arch Orthop Trauma Surg* 137(12):1623-1629.
- Schwarzkopf, R., T. Zamansani, M. Hoang, and T. Bridgeman. 2016. The effect of a clinical pathway strategy for managing care in total joint replacement: The impact of perioperative outcomes. *J Clin Exp Orthop* 2:11.
- Schwarzkopf, R., D. Phan, M. Hoang, S. Ross, and D. Mukamel. 2014. Do patients with income-based insurance have access to total joint arthroplasty? *J Arthroplasty* 29(6):1083-1086.
- Sharareh, B., N. Le, M. Hoang, and R. Schwarzkopf. 2014. Factors determining discharge destination for patients undergoing total joint replacement. *J Arthroplasty* 29(7):1355-1358.

## Book Chapter

- Kalmes, R.M., M.T. Donnell, K. Morris-Schaffer, and C.G. Scrafford. 2024. Proposition 65 and Exposure Assessment Methods. In: *Human and Ecological Risk Assessment, 3<sup>rd</sup> Edition*, Editors, D.J. Paustenbach. John Wiley & Sons, Inc., Hoboken, New Jersey.

## Published Abstracts

- Donnell, M.T., K.A. Keeton, L. Covell, and A.K. Madl. 2024. Oral Exposure to Titanium Dioxide (TiO<sub>2</sub>): Comparison of Adverse Outcome Pathway (AOP) Key Event (KE) Effect Levels to Human Daily Dietary Exposures. Poster presentation P190 at the Society of Toxicology (SOT) Annual Meeting & ToxExpo, Salt Lake City, UT; March 10-14, 2024. *Toxicologist* 198(S1):130. Abstract 3087.
- Madl, A.K., M.T. Donnell, and L. Covell. 2024. Synthetic Vitreous Fibers (SVFs): Adverse Outcome Pathways (AOPs) and Considerations for New Generation New Approach Methods (NAMs). Poster presentation P863 at the Society of Toxicology (SOT) Annual Meeting & ToxExpo, Salt Lake City, UT; March 10-14, 2024. *Toxicologist* 198(S1):492. Abstract 4288.
- Keeton, K.A., L. Covell, M.T. Donnell, and A.K. Madl. 2024. Comparison of In Vitro Nicotine Dissolution Profiles Across a Range of Oral Nicotine Products. Poster presentation P655 at the Society of Toxicology (SOT) Annual Meeting & ToxExpo, Salt Lake City, UT; March 10-14, 2024. *Toxicologist* 198(S1):441-442. Abstract 4121.
- Brown, S.E., J.J. Heywood, D.L. Eaton, M.T. Donnell, and D.J. Paustenbach. 2024. Risk Characterization of NDMA in Pharmaceuticals. Poster presentation P628 at the Society of Toxicology (SOT) annual Meeting & ToxExpo, Salt Lake City, UT; March 10-14, 2-24. *Toxicologist* 198(S1):620. Abstract 4715.
- Covell, L.T., M.T. Donnell, K.A. Keeton, and A.K. Madl. 2024. Human Health Risk Assessment of Per- and Polyfluoroalkyl Substances (PFAS) in Facial Cosmetics. Poster presentation P342 at the

- Society of Toxicology (SOT) Annual Meeting & ToxExpo, Salt Lake City, UT; March 10-14, 2024. *Toxicologist* 198(Late-Breaking S1):233-234. Abstract 5240.
- Massarsky, A., J.A. Parker, L. Gloeker, M.T. Donnell, N.R. Binczewski, J.S. Kozal, T. McKnight, A. Patterson, and M.L. Kreider. 2022. Assessing Potential Human Exposure to PFAS from Leave-In Dental Products. Poster Presentation at the Society of Toxicology (SOT) Annual Meeting & ToxExpo. March 27-31, 2022. San Diego, CA.
- Gibbs, K., R. Hwang, D. Dinh, M. Donnell, S. More, and E. Fung. 2022. Critical Evaluation of Chemicals Leached from PET and Recycled PET Beverage Containers into Beverages. Poster Presentation at the Society of Toxicology (SOT) Annual Meeting & ToxExpo. March 27-31, 2022. San Diego, CA.
- Brown, S.E., J.J. Heywood, G. Abele, M.T. Donnell, D.W. Brew, and D.J. Paustenbach. 2022. Investigation of Possible Cancer Risks Associated with Closed-System ENDS. Poster Presentation at the Society of Toxicology (SOT) Annual Meeting & ToxExpo. March 27-31, 2022. San Diego, CA.
- Paustenbach, D.J., G.R. Abele, J.J. Heywood, and M.T. Donnell. 2022. A Methodology for Estimating 4-ABP Dermal Intake via Contaminated Consumer Products. Poster Presentation at the Society of Toxicology (SOT) Annual Meeting & ToxExpo. March 27-31, 2022. San Diego, CA.
- Abele, G.R., J.J. Heywood, S.E. Brown, M.T. Donnell, D.W. Brew, and D.J. Paustenbach. 2022. Assessment of Possible Cardiovascular Risks Associated with Closed-System Electronic Nicotine Delivery System (ENDS) Aerosols. Poster Presentation at the Society of Toxicology (SOT) Annual Meeting & ToxExpo. March 27-31, 2022. San Diego, CA.
- Donnell, M.T., A. Massarsky, E. de Gandiaga, J.S. Kozal, L. Garnick, S.M. Bartell, J.A. Kubitz, and A.D. Monnot. 2021. Using E-FAST platform to predict human exposure to PFAS. Virtual Poster Presentation at the 2021 Society of Toxicology (SOT) Annual Meeting. March 12-26, 2021.
- Massarsky, A., M.T. Donnell, E. de Gandiaga, J.S. Kozal, L. Garnick, S.M. Bartell, J.A. Kubitz, and A.D. Monnot. 2021. Using ECOSAR and E-FAST platforms to predict ecological risks of PFAS. Virtual Poster Presentation at the 2021 Society of Toxicology (SOT) Annual Meeting. March 12-26, 2021.
- de Gandiaga, E., A. Hazell, A. Sharma, M. Donnell, A. Massarsky, A. Schulte, A. Bernal, and A.K. Madl. 2021. Exposure and human health risk of metals from electronic nicotine delivery systems. Abstract #2608. Virtual Poster Presentation at the 2021 Society of Toxicology (SOT) Annual Meeting. March 12-26, 2021.
- Hoang, M., K. Towle, A. Monnot, and E. Fung. 2020. Call for a Multi-Product Testing Strategy to Evaluate Potential Adverse Dermal Effects. Accepted abstract for Society of Toxicology (SOT) 59th Annual Meeting. March 15-19, 2020. Anaheim, California (conference cancelled due to COVID).
- Fung, E., K. Towle, M. Hoang, and A. Monnot. 2020. A Skin Sensitization Risk Assessment Framework for Evaluation of Metal Contamination in Personal Care Products. Accepted abstract for Society of Toxicology (SOT) 59th Annual Meeting. March 15-19, 2020. Anaheim, California (conference cancelled due to COVID).
- Massarsky, A., J. Parker, M. Hoang, E. Fung, and K. Unice. 2020. Using ToxCast and Reactome to Evaluate Toxicity of PFAS. Accepted abstract for Society of Toxicology (SOT) 59th Annual Meeting. March 15-19, 2020. Anaheim, California (conference cancelled due to COVID).
- Gloekler, L., L. Liang, S. More, N. Binczewski, M. Hoang, and A. Madl. 2020. Volatile Organic Compounds Measured in U.S. Indoor Residential Air from Smoking and Nonsmoking Homes

and Implications for Public Health. Accepted abstract for Society of Toxicology (SOT) 59th Annual Meeting. March 15-19, 2020. Anaheim, California (conference cancelled due to COVID).

Yang, L., R. Brewster, M. Hoang, and R. Novick. 2019. Exposure Assessment of Milk Protein in Non-Dairy or Vegan Ice Cream Substitutes – Are Non-Dairy or Vegan Products Safe to Populations with Milk Allergy? Poster Presentation at Society of Toxicology (SOT) Annual Meeting. March 10-14, 2019. Baltimore, MD.

Hoang, M., E. Fung, D. Drechsel, K. Towle, C. Poteete, D. Paustenbach, and A. Monnot. 2018. Screening-Level Safety Assessment of Personal Care Product Constituent Safety Using Publicly Available Data. Poster Presentation at Society of Toxicology (SOT) Annual Meeting. March 12-15, 2018. San Antonio, TX.

Schwarzkopf, R., M. Hoang, and D. Wright. 2016. Pain Catastrophizing as a Predictor for Post-Operative Pain and Opiate Consumption in Total Joint Arthroplasty Patients. Poster Presentation at the American Association of Hip and Knee Surgeons (AAHKS) Annual Meeting. November 10-13, 2016. Dallas, TX.

Schwarzkopf, R., D. Phan, M. Hoang, S. Ross, and D. Mukamel. 2014. Do Patients with Income-Based Insurance Have Access to Total Hip Arthroplasty? Poster Presentation at the Western Orthopaedic Association Annual Meeting. July 30 – August 2, 2014. Big Island, HI.

Sharareh, B., N. Le, M. Hoang, and R. Schwarzkopf. 2014. Factors Determining Discharge Destination for Patients Undergoing Total Joint Replacement. Poster Presentation at the Western Orthopaedic Association Annual Meeting. July 30 – August 2, 2014. Big Island, HI.

Schwarzkopf, R., D. Phan, M. Hoang, S. Ross, and D. Mukamel. 2014. Do Patients with Income-Based Insurance Have Access to Total Hip Arthroplasty? Poster Presentation at the American Orthopaedic Association Annual Meeting. June 18-21, 2014. Montreal, Canada.

Schwarzkopf, R., D. Phan, M. Hoang, D. Mukamel, and S. Ross. 2013. Do Patients with Income-Based Insurance Have Access to Total Hip Arthroplasty? Poster Presentation at the American Association of Hip and Knee Surgeons (AAHKS) Annual Meeting. November 8-10, 2013. Dallas, TX.

## **Presentations**

Donnell, M.T., K.A. Keeton, L. Covell, and A.K. Madl. 2024. Oral Exposure to Titanium Dioxide (TiO<sub>2</sub>): Comparison of Adverse Outcome Pathway (AOP) Key Event (KE) Effect Levels to Human Daily Dietary Exposures. Poster presentation P190 at the Society of Toxicology (SOT) Annual Meeting & ToxExpo Annual Meeting in Salt Lake City, UT. March 10-14, 2024.

Donnell, M.T., A. Massarsky, E. de Gandiaga, J.S. Kozal, L. Garnick, S.M. Bartell, J.A. Kubitz, and A.D. Monnot. 2021. Using E-FAST platform to predict human exposure to PFAS. Virtual poster presentation at the 2021 Society of Toxicology (SOT) Annual Meeting. March 12-26, 2021.

Hoang, M., R. Novick, M. Lancer, and A. Wagstaff. 2019. Glyphosate: Emerging Litigation Trends. Webinar Presentation at Perrin Conferences. May 23, 2019.

Hoang, M. and G. Gray. 2017. The Effect of Anatase Titanium Dioxide Nanoparticles via Intranasal Instillation on Oxidative Stress in Mice Brain: A Systematic Review. Poster presented at GW Research Days. Washington, D.C.

Hoang, M. and G. Gray. 2016. Understanding the Database Uncertainty Factor (UFD). Podium Presentation within symposium “Dose Response Modeling for Human Health Risk Assessment (III)” at the Society for Risk Analysis (SRA) Annual Meeting in San Diego, CA. December 11-15, 2016.



## Magazine Article

Jacobs, N., A. Urban, D. Dinh, M. Donnell, A. Schulte, and R. Ramirez. Improving the Safety of Meal Kits: A Holistic Approach. Food Safety Magazine. October 18, 2021. Available at: <https://www.food-safety.com/articles/7395-improving-the-safety-of-meal-kits-a-holistic-approach>.