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Engineering & Scientific Consulting

Carolyn Scrafford, Ph.D., M.P.H.

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Professional Profile

Dr. Scrafford has over 20 years of multi-disciplinary experience in epidemiological methods, applied statistics, and risk assessment to evaluate the human health effects of food contaminants and additives, nutrients, and environmental compounds in the U.S. as well as Europe and other international settings. She has designed, conducted, and analyzed data from national, market basket, customized surveys on food consumption patterns and has experience in using that data to conduct dietary risk assessments for food ingredients, nutrients, heavy metals, and contaminants.

Dr. Scrafford has developed GRAS notifications, Food Additive Petitions (FAPs), and Color Additive Petitions (CAPs) in support of pre-market approval submissions to the U.S. FDA as well as regulatory submissions to other international authoritative bodies by providing evaluations of the human safety data and conducting dietary exposure assessments. The exposure assessments are based on a variety of large databases from the US and other countries including NHANES (National Health and Nutrition Examination Survey), the United Kingdom's National Diet and Nutrition Survey (NDNS), EFSA's Comprehensive European Food Consumption Database, and USAID's Demographic and Health Surveys (DHS). As part of these submissions, Dr. Scrafford communicates complex scientific information directly with federal regulators and other key stakeholders.

Dr. Scrafford also provides technical and expert support related to dietary exposure to food toxins and contaminants including lead, cadmium, inorganic arsenic, and acrylamide. Dr. Scrafford has expertise in designing sampling protocols with the objective to determine levels of components and contaminants in food products currently in the market place. Dr. Scrafford is responsible for analyzing the survey results to estimate the concentration of the contaminants in the food that is combined with consumption data to estimate consumer exposure to these compounds through the diet. As part of this work, Dr. Scrafford has presented and testified on topics related to statistics, dietary consumption patterns, dietary exposure, and risk assessment.

Dr. Scrafford has expertise in the synthesis of epidemiological evidence to both quantitatively and qualitatively evaluate causal associations between dietary and environmental exposures and health outcomes. With a background in epidemiological methods and analysis, Dr. Scrafford has expertise in the synthesis of epidemiological evidence to both quantitatively and qualitatively evaluate causal associations between dietary and environmental exposures and health outcomes. Scrafford has evaluated study protocols for clients conducting clinical trials designed to measure the association between novel food and dietary supplement products on specific health outcomes including weight loss and gastrointestinal health in support of safety and efficacy evaluations. She has also collaborated with academic institutions to investigate the association between dietary patterns and health outcomes using data from ongoing prospective cohort studies.

Academic Credentials & Professional Honors

MHS, Biostatistics, Johns Hopkins University, 2013

Ph.D., International Health, Johns Hopkins University, 2013

M.P.H., Public Health, Johns Hopkins University, 2004

B.S., Biology, Colgate University, 1999

Professorial Lecturer, Global Health, George Washington University, 2019 - present

Delta Omega Scholarship Award, 2011

Johns Hopkins Center for Global Health Field Research Award, 2011

National Institutes of Health Training Grant in International Maternal and Child Health, 2008-2010

Postdoctoral Scholar, Global Disease Epidemiology and Control, Johns Hopkins University, 2014

Professional Affiliations

International Epidemiological Association

American College of Epidemiology

American Society for Nutrition

Institute of Food Technologists

Institute of Food Technologists

Publications

Bi X, Davis BJK, Barraij LM, Srinivasan D, Mahadev P, Mathew P, Mishra D, Scrafford CG, Tran NL, Jack MM. Beverage Consumption Patterns among U.S. Adolescents and Adults from a New 24-h Beverage Recall Survey Compared to the National Health and Nutrition Examination Survey (NHANES) 2017-2018. *Nutrients*. 2023 Aug 12;15(16):3561. doi: 10.3390/nu15163561.

Higgins KA, Bi X, Davis BJ, Barraij LM, Scrafford CG, Murphy MM. Adequacy of total usual micronutrient intakes among pregnant women in the United States by level of dairy consumption, NHANES 2003-2016. *Nutr Health*. 2022 Dec;28(4):621-631. doi: 10.1177/02601060211072325. Epub 2022 Feb 8.

Davis BJK, Bi X, Higgins KA, Scrafford CG. Gestational Health Outcomes Among Pregnant Women in the United States by Level of Dairy Consumption and Quality of Diet, NHANES 2003-2016. *Matern Child Health J*. 2022 Oct;26(10):1945-1952. doi: 10.1007/s10995-022-03469-4. Epub 2022 Aug 8.

Badding MA, Barraij L, Williams AL, Scrafford C, Reiss R. CLARITY-BPA Core Study: Analysis for non-monotonic dose-responses and biological relevance. *Food Chem Toxicol*. 2019 Sep;131:110554. doi: 10.1016/j.fct.2019.06.001. Epub 2019 Jun 15.

Barraij L, Scrafford C, Bi X, Tran N. Intake of low and no-calorie sweeteners (LNCS) by the Brazilian population. *Food Addit Contam Part A Chem Anal Control Expo Risk Assess*. 2021 Feb;38(2):181-194. doi: 10.1080/19440049.2020.1846083. Epub 2020 Dec 18.

Murphy MM, Scrafford CG, Barraij LM, Bi X, Higgins KA, Jaykus LA, Tran NL. Potassium chloride-based

replacers: modeling effects on sodium and potassium intakes of the US population with cross-sectional data from NHANES 2015-2016 and 2009-2010. *Am J Clin Nutr*. 2021 Jul 1;114(1):220-230. doi: 10.1093/ajcn/nqab020.

Barraj L, Scrafford C, Bi X, Tran N. Intake of low and no-calorie sweeteners (LNCS) by the Brazilian population. *Food Addit Contam Part A Chem Anal Control Expo Risk Assess*. 2021 Feb;38(2):181-194. doi: 10.1080/19440049.2020.1846083. Epub 2020 Dec 18. PMID: 33337974

Scrafford CG, Bi X, Multani JK, Murphy MM, Schmier JK, Barraj LM. Health Care Costs and Savings Associated with Increased Dairy Consumption among Adults in the United States. *Nutrients* 2020, 12(1), 233; <https://doi.org/10.3390/nu12010233>

Barraj LM, Bi X, Murphy MM, Scrafford CG, Tran NL. Comparisons of Nutrient Intakes and Diet Quality among Water-Based Beverage Consumers. *Nutrients*. 2019 Feb 1;11(2). pii: E314. doi: 10.3390/nu11020314.

Scrafford CG, Bi X, Multani JK, Murphy MM, Schmier JK, Barraj LM. Health Economic Evaluation Modeling Shows Potential Health Care Cost Savings with Increased Conformance with Healthy Dietary Patterns among Adults in the United States. *J Acad Nutr Diet*. 2019 Apr;119(4):599-616. doi: 10.1016/j.jand.2018.10.002. Epub 2018 Dec 24.

Bastaki M, Farrell T, Bhusari S, Bi X, Scrafford C. Estimated daily intake and safety of FD&C food-colour additives in the US population. *Food Addit Contam Part A Chem Anal Control Expo Risk Assess*. 2017 Jun;34(6):891-904. doi: 10.1080/19440049.2017.1308018. Epub 2017 Apr 19. PubMed PMID: 28332449.

Scrafford CG, Barraj LM, Tsuji JS. Considerations when using longitudinal cohort studies to assess dietary exposure to inorganic arsenic and chronic health outcomes. *Food Chem Toxicol*. 2016 Jul;93:111-8. doi: 10.1016/j.fct.2016.05.003. Epub 2016 May 5. Review. PubMed PMID: 27155067.

Scrafford CG, Tielsch JM. Maternal Deaths Account for a Small Proportion of the Total Deaths Among Reproductive Age Women. *J Womens Health (Larchmt)*. 2016 Mar;25(3):242-8. doi: 10.1089/jwh.2015.5402. Epub 2016 Mar 3. PubMed PMID: 26938968.

Scrafford CG, Barraj LM, Tsuji JS. Considerations when using longitudinal cohort studies to assess dietary exposure to inorganic arsenic and chronic health outcomes. *Food Chem Toxicol*. 2016 Jul;93:111-8.

Scrafford CG, Tielsch JM. Maternal deaths account for a small proportion of total deaths among reproductive age women in low and middle income countries: A retrospective cohort study. *Journal of Women's Health*. Accepted to be published May 2016.

Ojo KD, Soneja SI, Scrafford CG, Khatry SK, LeClerq SC, Checkley W, Katz J, Breyse PN, Tielsch JM. Indoor particulate matter concentration, water boiling time, and fuel use of selected alternative cookstoves in a home-like setting in rural Nepal. *Int J Environ Res Public Health*. 2015 Jul 7;12(7):7558-81. doi: 10.3390/ijerph120707558.

Tran NL, Barraj LM, Scrafford C, Bi X, Troxell T. Partitioning of dietary metal intake—A metal dietary exposure screening tool. *Risk Anal*. 2015 May;35(5):872-81. doi: 10.1111/risa.12322. Epub 2014 Dec 24.

Ahmed S, Li Q, Scrafford C, Pullum TW. An assessment of DHS maternal mortality data and estimates. *DHS Methodological Reports No. 13*, CF International, Rockville, MD, 2014.

Tran NL, Barraj LM, Heilman JM, Scrafford CG. Egg consumption and cardiovascular disease among diabetic individuals: A systematic review of the literature. *Diabetes, Metabolic Syndrome and Obesity* 2014 Mar; 7:121-137.

Scrafford CG, Mullany LC, Katz J, Khatry SK, LeCLerq SC, Darmstadt GL, Tielsch JM. Incidence and risk factors for neonatal jaundice among newborns in southern Nepal. *Tropical Medicine & International Health* 2013; 18(11):1317-1328.

Gurung A, Scrafford CG, Tielsch JM, Levine OS, Checkley W. Computerized lung sound analysis as diagnostic aid for the detection of abnormal lung sounds: A systematic review and meta-analysis. *Respiratory Medicine* 2011 Sep; 105(9):1396-403. Epub 2011 Jun 14. Review.

Scrafford CG, Tran NL, Barraij LM, Mink PJ. Egg consumption and CHD and stroke mortality: A prospective study of US adults. *Public Health Nutrition* 2011 Feb; 14(2):261-270.

Barraij LM, Scrafford CG, Eaton WC, Rogers RE, Jeng CJ. Arsenic levels in wipe samples collected from play structures constructed with CCA-treated wood: Impact on exposure estimates. *Science of the Total Environment* 2009 Apr 1; 407(8):2586-2592.

Barraij LM, Scrafford CG, Lantz J, Daniels C, Mihlan G. Within-day drinking water consumption patterns: Results from a drinking water consumption survey. *Journal of Exposure Science and Environmental Epidemiology* 2009; 19:382-395.

Sanchez CA, Barraij LM, Blount BC, Scrafford CG, Valentin-Blasini L, Smith KM, Krieger RI. Perchlorate exposure from food crops produced in the lower Colorado River region. *Journal of Exposure Science and Environmental Epidemiology* 2009 May; 19(4):359-368.

Cutler GJ, Nettleton JA, Ross JA, Harnack LJ, Jacobs DR, Scrafford CG, Barraij LM, Mink PJ, Robien K. Dietary flavonoid intake and risk of cancer in post-menopausal women: The Iowa Women's Health Study. *International Journal of Cancer* 2008; 123:664-671.

Barraij LM, Tsuji JS, Scrafford CG. The SHEDS-Wood Model: Incorporation of observational data to estimate exposure to arsenic for children playing on CCA-treated wood structures. *Environmental Health Perspectives* 2007; 115:781-786.

Mink PJ, Scrafford CG, Barraij LM, Harnack L, Hong CP, Nettleton JA, Jacobs DR. Flavonoid intake and cardiovascular disease mortality: A prospective study in postmenopausal women. *American Journal of Clinical Nutrition* 2007; 85:895-909.

Erdreich LS, Van Kerkhove MD, Scrafford CG, Barraij L, McNeely M, Shum M, Sheppard AR, Kelsh M. Factors that influence the radiofrequency power output of GSM mobile phones. *Radiation Research* 2007; 168:253-261.

Tsuji JS, Yost LJ, Barraij LM, Scrafford CG, Mink PJ. Use of background inorganic arsenic exposures to provide perspective on risk assessment results. *Regulatory Toxicology and Pharmacology* 2007; 48:59-68.

Nettleton JA, Harnack LJ, Scrafford CG, Mink PJ, Barraij LM, Jacobs DR. Dietary flavonoids and flavonoid-rich foods are not associated with risk of Type 2 Diabetes in postmenopausal women. *The Journal of Nutrition* 2006; 136:3039-3045.

Loretz LJ, Api AM, Barraij LM, Burdick J, Davis DA, Dressler WE, Gilberti E, Jarrett G, Mann S, Pan YHL, Re TA, Renskers KJ, Scrafford CG, Vater S. Exposure data for cosmetic products: Hairspray, spray perfume, liquid foundation, shampoo, body wash, and solid antiperspirant. *Food and Chemical Toxicology* 2006; 44:2008-2018.

Goodman M, Teta MJ, Hessel PA, Garabrant DH, Craven VA, Scrafford CG, Kelsh MA. Mesothelioma and lung cancer among motor vehicle mechanics: A meta-analysis. *Annals of Occupational Hygiene* 2004; 48(4):309-326.

Loretz LJ, Api AM, BarraJ LM, Burdick J, Dressler WE, Gettings SD, Han Hsu H, Pan YHL, Re TA, Renskers KJ, Rothenstein A, Scrafford CG, Sewall C. Exposure data for cosmetic products: Lipstick, body lotion, and face cream. *Food and Chemical Toxicology* 2005; 43:279-291.

Book Chapter

Renee M. Kalmes, Keith Morris-Schaffer, and Carolyn G. Scrafford. Proposition 65 and Exposure Assessment Methods. Chapter in: *Human and Ecological Risk Assessment: Theory and Practice* (3rd Edition).

Presentations

Scrafford CG. A Holistic Look at Consumer Exposure to Lead, Cadmium and Arsenic, including Vulnerable Populations. JIFSAN-CFS3 Advisory Council Virtual Annual Symposium Understanding of the Impact of Arsenic, Cadmium, and Lead Across the Food Supply. May 25, 2022.

Scrafford CG. Recent Trends in Food and beverage litigation. Panel Discussion at ABA Toxic Tort and Environmental Law Conference. April 6, 2019. Coronado, California.

Scrafford CG. Application of epidemiology data on dietary components and cancer outcomes in public health policy. GMA Science Forum, April 19, 2017. Washington DC.

Scrafford CG. Data needs and approaches for estimating exposure to FD&C color additives in the US population. IFT Annual Meeting, June 2017. Las Vegas, Nevada.

Scrafford CG, Tran N. Overview of the Current State of the Science of Dietary Exposure Assessment. ILSI Annual Meeting, January 25, 2016. St. Petersburg, Florida.

Ahmed S, Li Q, Scrafford C, Pullum TW. The extent of underestimation of maternal mortality in developing countries from demographic and health surveys (DHS) data. Platform presentation, Population Association of American Annual Meeting, San Diego, CA, April 30-May 2, 2015.

Smerling J, Balentine D, Kearney M, Scrafford CG, BarraJ L, Xiaoyu Bi. Contribution of nutrients from consumption of low/non-fat/light ice cream and frozen yogurt versus regular ice cream to total daily nutrient intake. Accepted for presentation at Epidemiology and Prevention / Nutrition, Physical Activity and Metabolism 2012 Scientific Sessions, San Diego, CA, March 2012.

Scrafford CG, BarraJ LM, Tran NL, Mink PJ. Egg consumption and CHD and stroke mortality: a prospective study of US adults. Presented at the 2009 Experimental Biology Annual Meeting, New Orleans, LA, 2009.

Scrafford CG, BarraJ L, Tran N. Nutrient deficiency classification bias relating to dietary recall: A case-study with dietary and red blood cell folate in UK young people (4-18 years). Presented at the 2006 International Society of Exposure Analysis, Paris, France, 2006.

Habig C, Scrafford CG. Additional factors for inclusion in higher tier avian and mammalian risk assessments. Society of Environmental Toxicology and Chemistry, Europe Annual Meeting, May 2006.

Habig C, Scrafford CG. Pesticide residues in invertebrate prey items: From sampling to data analysis for non-target organism risk assessments. Society of Environmental Toxicology and Chemistry, Europe Annual Meeting, May 2005.

Tsuji J, Van Kerkhove M, Scrafford C, Kaetzel R. Biomonitoring of a community for soil arsenic exposure. Presented at the 2005 Society of Toxicology Conference, March 2005.

BarraJ L, Johnston J, Scrafford C. Investigating the impact of certain assumptions on estimates of long-

term occupational exposure to agricultural pesticides. Presented at the 2004 Annual Society for Risk Analysis Meeting, Palm Springs, CA, December 2004.

Erdreich LS, Van Kerkhove MD, McNeely M, Scrafford C, Barraj L. Factors affecting output power (and radiofrequency exposure) of GSM mobile phones. Presented at BEMS, June 2004.

Scrafford C, Barraj L. The use of bone biomarkers to identify osteoporosis intervention groups in pre-adolescents and adolescents. Presented at the 23rd Annual Meeting for the Society for Risk Analysis, Baltimore, MD, December 7-10, 2003.

Barraj L, Scrafford C, Walls C, Johnston J. Comparison of three approaches to derive estimates of longitudinal exposures using short-term data. Presented at the 2002 International Society of Exposure Analysis/International Society for Environmental Epidemiology Annual Conference, Vancouver, British Columbia, Canada, 2002.

Barraj L, Walls C, Scrafford C, Johnston J. Impact of between and within person variability on estimates of longitudinal exposures using short-term data. Presented at the 2002 International Society of Exposure Analysis/International Society for Environmental Epidemiology Annual Conference, Vancouver, British Columbia, Canada, 2002.

Johnston JE, Scrafford C, Daniels CL. An examination of exposure database limitations. Presented at the 2002 International Society of Exposure Analysis/International Society for Environmental Epidemiology Annual Conference, Vancouver, British Columbia, Canada, 2002.

Barraj L, Francis M, Scrafford C. Biomonitoring data from the priority toxicant reference range study. Presentation at the International Society of Exposure Analysis, Charleston, SC, November 2001.

Walls CL, Petersen BJ, Scrafford C, Barraj LM. Calendar model methodologies for assessing drinking water exposure. Presentation at the International Society of Exposure Analysis, Charleston, SC, November 2001.

Gestational Health Outcomes Among Pregnant Women in the United States by Level of Dairy Consumption and Quality of Diet, NHANES 2003-2016.

Gestational Health Outcomes Among Pregnant Women in the United States by Level of Dairy Consumption and Quality of Diet, NHANES 2003-2016.

Davis BJK, Bi X, Higgins KA, Scrafford CG. *Matern Child Health J.* 2022 Oct;26(10):1945-1952. doi: 10.1007/s10995-022-03469-4. Epub 2022 Aug 8.

Davis BJK, Bi X, Higgins KA, Scrafford CG. *Matern Child Health J.* 2022 Oct;26(10):1945-1952. doi: 10.1007/s10995-022-03469-4. Epub 2022 Aug 8.

Higgins KA, Bi X, Davis BJ, Barraj LM, Scrafford CG, Murphy MM. *Nutr Health.* 2022 Dec;28(4):621-631. doi: 10.1177/02601060211072325. Epub 2022 Feb 8.

Higgins KA, Bi X, Davis BJ, Barraj LM, Scrafford CG, Murphy MM. *Nutr Health.* 2022 Dec;28(4):621-631. doi: 10.1177/02601060211072325. Epub 2022 Feb 8.

Adequacy of total usual micronutrient intakes among pregnant women in the United States by level of dairy consumption, NHANES 2003-2016.

Adequacy of total usual micronutrient intakes among pregnant women in the United States by level of dairy consumption, NHANES 2003-2016.

CLARITY-BPA Core Study: Analysis for non-monotonic dose-responses and biological relevance.

Badding MA, Barraj L, Williams AL, Scrafford C, Reiss R. Food Chem Toxicol. 2019 Sep;131:110554. doi: 10.1016/j.fct.2019.06.001. Epub 2019 Jun 15.

CLARITY-BPA Core Study: Analysis for non-monotonic dose-responses and biological relevance. Badding MA, Barraj L, Williams AL, Scrafford C, Reiss R. Food Chem Toxicol. 2019 Sep;131:110554. doi: 10.1016/j.fct.2019.06.001. Epub 2019 Jun 15.

Murphy MM, Scrafford CG, Barraj LM, Bi X, Higgins KA, Jaykus LA, Tran NL. Am J Clin Nutr. 2021 Jul 1;114(1):220-230. doi: 10.1093/ajcn/nqab020.

Murphy MM, Scrafford CG, Barraj LM, Bi X, Higgins KA, Jaykus LA, Tran NL. Am J Clin Nutr. 2021 Jul 1;114(1):220-230. doi: 10.1093/ajcn/nqab020.

Potassium chloride-based replacers: modeling effects on sodium and potassium intakes of the US population with cross-sectional data from NHANES 2015-2016 and 2009-2010.

Potassium chloride-based replacers: modeling effects on sodium and potassium intakes of the US population with cross-sectional data from NHANES 2015-2016 and 2009-2010.

Project Experience

Provided expert testimony related to dietary exposure assessment in support of clients' defense of their food products in several trials related to California's Proposition 65.

Wrote, reviewed, and critiqued study protocols for clinical trials designed to evaluate association between novel food and dietary supplement products and health outcomes.

Conducted nutritional epidemiological research and analysis to investigate the potential association between dietary components (e.g., flavonoids, eggs) and heart health.

Conducted dietary risk assessments in support of Proposition 65 cases for acrylamide, lead, 4-MEI, and caffeine.

Conducted analyses to measure how environmental factors and characteristics of cell phone use affect radiofrequency (RF) power output, a surrogate measure of individual exposure from mobile phone use.

Analyzed data from a community study investigating the relationship between arsenic found in soil and arsenic in urine among young children.

Analyzed data on lead levels in chocolate and other candies in support of a Proposition 65 case to determine the source of the lead and potential dietary exposure among candy consumers in the US population.

Conducted epidemiological analyses on data from a community study to determine SIRs based on Census records to account for non-response and potential biases in the study population.

Conducted research on the association of diet components and health status. The research objective is to support potential claims by a major food company.

Analyzed microbial growth data and developed predictive microbial models to be used to support proposed new processing methods for food products.

Analyzed data from several surveys of consumer products use and developed summary distributions for use in risk assessments of compounds/contaminants in these consumer products.

Peer Reviews

American Journal of Clinical Nutrition

International Scholarly Research Notices

Journal of Cardiovascular Pharmacology

Nutrients

Current Nutrition and Food Science

Food Chemical Toxicology