

# Jonathan D. Urban, Ph.D., DABT

SENIOR MANAGING SCIENTIST

### CONTACT INFORMATION

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### PROFESSIONAL PROFILE

Dr. Jonathan Urban is a Senior Managing Scientist in ToxStrategies' Health Sciences practice. He is a boardcertified toxicologist with more than 15 years' experience studying and evaluating the potential human health effects and risks associated with personal, occupational, and community-wide exposures to soil, water, and air contaminants, including chemical and petrochemical production activities and criteria air pollutants. He specializes in using evidence-based methods in support of hazard and risk assessment and is involved in the firm's integration of these methods in the safety assessment development process. He has played an integral role in the firm's efforts to develop and apply comprehensive systematic review methods for chemical risk assessment, with experience in all aspects of systematic review, including using critical appraisal tools for evaluating studies for risk of bias and external validity, as well as evidence integration. Dr. Urban has utilized this expertise in the development of critiques and recommendations regarding health-based toxicity criteria for both state and federal regulatory agencies, industry, and private-sector stakeholders. Dr. Urban also has extensive experience conducting both screening-level and complex site-specific risk assessments and has developed a comprehensive knowledge base on a variety of regulatory guidance documents on human health risk assessment. This experience has also facilitated work with regulatory agencies and potentially responsible parties on developing site cleanup standards. Additionally, Dr. Urban has experience in the drug development and food safety sectors, providing monitoring oversight for studies in support of the United States Food and Drug Administration (FDA)'s pre-IND application process for pharmaceuticals and conducting GRAS reviews for food additives, respectively.

Dr. Urban is a Diplomate of the American Board of Toxicology, has published academic and professional studies in the peer-reviewed literature, and is a reviewer for various scientific journals. While earning his Ph.D. in toxicology at the University of North Carolina at Chapel Hill, Dr. Urban served as an enlisted communications specialist in the United States Marine Corps Reserves (Communications Company, Greensboro, NC).









### EDUCATION AND DEGREES EARNED

2006 Ph.D., Toxicology, University of North Carolina at Chapel Hill

1999 B.S., Biological Sciences, University of Maryland at College Park

## PROFESSIONAL ASSOCIATIONS AND AWARDS

Diplomate of the American Board of Toxicology (DABT) (since 2013; recertified 2018 and 2023)

Society of Toxicology (since 2004): 2006 Graduate Student Travel Award

Risk Assessment Specialty Section, SOT (since 2008)

Reproductive and Developmental Toxicology Specialty Section, SOT (since 2019)

Carcinogenesis Specialty Section, SOT (since 2021)

American College of Toxicology (2012-2014)

Society of Environmental Toxicology and Chemistry (2011; 2023)

Society for Neurosciences (student member 2003–2005)

#### PROFESSIONAL ACTIVITIES

2025-Present	Associate Editor: Toxicology Reports
2024-Present	Risk Assessment Specialty Section's Risk Assessment Syllabus Committee Member
2019–2025	Editorial board member: Toxicology Reports
2022-2024	Secretary/Treasurer for SOT's Carcinogenesis Specialty Section
2017–2020	Scientific Review Panel (Permanent Member): National Library of Medicine's Hazardous Substances Data Bank
2016–2017	Scientific Review Panel (Invited Guest): National Library of Medicine's Hazardous Substances Data Bank. Meetings #97 (September 2016) and #98 (January 2017)
2013	Co-chaired SOT Continuing Education Course: Approval of Biosimilar Monoclonal Antibodies: Scientific, Regulatory and Legal Challenges (AM04)

#### SELECTED PEER REVIEW

[Web of Science ResearcherID: <u>I-5896-2019</u>]

Environmental Toxicity and Chemistry

Toxicological Sciences

Food and Chemical Toxicology

Regulatory Toxicology and Pharmacology

Environment International

Environmental Science and Technology

Human and Experimental Toxicology

Molecular Pharmacology

Mutation Research/Genetic Toxicology and Environmental Mutagenesis

Neuropsychopharmacology





Toxicology Reports
Journal of Food Biochemistry
Journal of Pharmacological and Experimental Therapeutics

## SELECTED PROJECT EXPERIENCE

## Toxicology and Risk Assessment

Currently providing technical support on toxicology, environmental sampling, and risk assessment at a former railroad wood treatment site under an ASAOC Removal Site Evaluation. Worked with stakeholders, the United States Environmental Protection Agency (EPA) Region 6 and state regulators to develop soil and vapor intrusion sampling plans for characterizing the presence and potential hazards and risks of several chemicals of potential concern (COPCs) (including VOCs, PAHs, PCP, and dioxins/furans) at local off-site residential properties, schools, public parks, and community centers. Used sampling data to characterize potential exposures and to develop a human health risk evaluation that will be used to inform potential risk management steps.

Manager and lead toxicologist on a large project researching and developing proposed health-based thresholds in support of water quality standards protective of human health and aquatic life for a state regulatory agency. This project involved researching health-based literature for over 250 priority contaminants of emerging concern (CECs) and was conducted to support the agency's exploration into expanding state water resources.

Researched and developed a proposed relative oral bioavailability (RBA) value for soil dioxins and furans for a remediation site risk evaluation in EPA Region 6. A site-specific congener profile, along with a summary of the relevant research (in vivo, in vitro) and pertinent state regulatory precedence, was presented in a state-of-the-science assessment to justify a best-science soil dioxin RBA value as an alternative to EPA's default.

Submitted technical comments to EPA's Offices of Chemical Safety and Pollution Prevention's (OCSPP's) and Pollution Prevention and Toxics' (OPPT's) regarding their 2022 Draft Proposed Principles of Cumulative Risk Assessment (CRA) report, which presented a generalized overview of OCSPP/OPPT's plans for cumulative risk evaluations under the Toxic Substances Control Act (TSCA). Also reviewed and provided technical recommendations regarding EPA's 2023 Draft Guidelines for Cumulative Risk Assessment Planning and Problem Formulation.

In response to a state request, provided oversight on an effort to review existing health-based screening levels and toxicity factors from the Unregulated Contaminant Monitoring Rule 4 (UCMR4) list of cyanotoxins plus dihydroanatoxin-a, and develop health-based screening levels and toxicity factors where the data were sufficient. The resulting research was summarized in a report to the state and presented at subsequent scientific conference.

Researched and composed sections on the characterization of dioxin toxicology, toxic equivalency factors, dioxin oral bioavailability, and risk characterization for risk assessments on behalf of stakeholders working with regulators at remediation sites in EPA Regions 2 and 5.

Project manager for research evaluating a state's 1-in-100,000 individual-chemical target excess risk level used for contaminated site cleanup to the individual-chemical excess risk levels in comparison with EPA and state regulatory agencies. The research involved collecting and reviewing Record of Decisions (RODs) and similar/related records (e.g., baseline human health risk assessments) for all federal Superfund sites in EPA Region 6, including former and current National Priority List (NPL) sites, as well as state Superfund program sites in EPA Region 6 states.

Conducted and published a comprehensive human health hazard and cancer risk assessment on the ingestion of fish sampled from the Lower Passaic River. This evaluation included more than 150 chemicals of potential concern, including PCDD/Fs, PCBs, metals, and several other organic compounds, and used peer-reviewed site-specific exposure and consumption data to reduce assessment uncertainty.





Analyzed toxicogenomics data from an *in vivo* bioassay that incorporated comprehensive dose-response study design to derive estimates of relative potency (REPs) for dioxin-like compounds, comparing these early-stage genomics-based REPs with those that had been reported using later stage endpoints (e.g., protein activity, pathological events, etc.).

Composed a state-of-the-science toxicology report in support of updating an outdated but commonly used reference dose (RfD) for copper, based on chronic exposure scenarios. Critical human and animal studies were identified from a comprehensive review of the literature and used to develop an updated RfD. The report was submitted to a state environmental regulatory agency, and the recommendations made in this report led the state regulatory agency to update the toxicity value used as the basis of risk-based environmental exposure limits for copper (e.g., Cu-contaminated soils).

In a project involving legacy antimony (Sb) smelter operations, performed extensive research on the toxicology and bioavailability of various forms of antimony, the results of which were submitted to a state environmental regulatory agency in the form of state-of-the-science reports. The recommendations made in these reports led the state regulatory agency to update the toxicity values used as the basis of risk-based environmental exposure limits for antimony (e.g., Sb-contaminated soils).

Evaluated the potential impact of toxicological effects in rodents observed in NTP's 2016 antimony trioxide ( $Sb_2O_3$ ) inhalation bioassay report on the state soil cleanup level using preliminary benchmark dose (BMD) analytical estimates of noncancer and cancer endpoint potencies.

Project manager for the evaluation of perfluoronanonoic acid (PFNA), 1,4-dioxane, and 1-methylnaphthalene toxicology, in support of an effort to provide a state regulatory agency with state-of-the-science alternatives for deriving toxicity values to serve as the basis for establishing water criteria.

Managed and conducted an analytical assessment of PCNs, PCDD/Fs, and dioxin-like PCBs based on sediment sampling for a prominent harbor water body in the northeastern United States. Used preliminary TCDD-based toxic equivalency factors (TEFs) for PCN congeners to characterize PCN contribution to overall sample TEQs. Employed PCA fingerprinting analyses to compare PCN congener profiles between sediment and technical mixtures in an effort to identify potential PCN sources.

Provided toxicological expertise in a comprehensive analysis of impacts to an urban area in North Texas from shale gas drilling and production.

Conducted comprehensive literature reviews on the human health effects of multiple nickel and lead compounds in support of the European Union's Registration, Evaluation & Authorisation of Chemicals (REACH) initiative, and populated the International Uniform Chemical Information Database (IUCLID) with relevant substance-specific data. Evaluated key studies for reliability and relevance, synthesized large volumes of data, and generated integrative reports.

## Criteria Pollutants and Air Toxics

Provided toxicological support on a large epidemiology study for a state regulatory agency which evaluated the potential associations between residential proximity to refineries and health outcomes for data between 2000-2019. Air modeling analyses based on federally reported facility emissions was used to define census tracts of interest, the health outcomes of which were compared to in-state control census tracts matched on demographic and socioeconomic characteristics. The study was approved by the state department of health's Institutional Review Board, and the comparative health outcome analyses were based on birth defects, cancer, and asthmarelated hospitalizations data obtained from the state registries.

Provided expert testimony at a Mississippi Department of Environmental Quality (MDEQ) administrative hearing in support of a modified construction permit and a proposed Title V air permit for a wood pellet manufacturing facility (Permit Nos. 0080–00031 and 00800-00050) regarding the potential residential health impacts of the primary hazardous air pollutants from the facility emissions. Utilized air dispersion modeling of facility stack test data to





characterize residential exposures relative to health protective exposure levels developed by multiple regulatory and public health agencies (e.g., EPA, TCEQ, CalEPA, and ATSDR).

Researched and submitted technical comments to EPA's OCSPP and OPPT regarding the pre-prioritization of styrene and ethylbenzene as candidate chemistries for designation as High-Priority Substances for risk evaluation under Section 6 of the Toxic Substances Control Act (TSCA). The comments focused on key publications and research materials regarding the hazard, dose-response, and exposure scenarios for each chemistry.

Provided expert testimony in two Texas state contested case hearings of air permits (one for Permit Numbers 22052, PSDTX1578, GHGPSDTX201, 46307, PSD-TX1580, GHGPSDTX202, 46426, PSD-TX999M1, GHGPSDTX203, 19806 and PSD-TX1586; the other for Permit Numbers 158420 and PSDTX1572) and provided litigation support in another (Permit Numbers 38754 and PSDTX324M14). Cases involved the permitting of criteria (NO2, PM10, and PM2.5) and non-criteria pollutant emissions approved by the Texas Commission on Environmental Quality (TCEQ) for facilities in the chemical industry. Utilized air dispersion modeling and air monitoring analysis to characterize community exposures relative to EPA's National Ambient Air Quality Standards (NAAQS) and TCEQ's Effects Screening Levels (ESLs) to address concerns about potential health effects.

Provided expertise in the areas of toxicology and risk assessment regarding the emissions from, and air monitoring of, two separate petrochemical facilities in support of two additional Texas state air permits that were under consideration for contested case hearings. In these efforts, risk assessment tools were applied to federal and state monitoring and emissions modeling data and used to develop public communication briefs for area community stakeholders who attended public meetings hosted by the state regulatory agency.

Evaluated risk assessments for ethylene oxide prepared by EPA and state regulatory agencies regarding potential air exposures in communities and to workers living and working near sterilizer facilities across the United States. Prepared comments describing shortcomings and limitations of the federal methods for characterizing exposures and evaluating potential health risks.

Provided toxicology support in the development of expert opinions on the available toxicology data used as the basis for National Ambient Air Quality Standards (NAAQS) for NO2, SO2, and PM10 with regard to respiratory effects in humans.

Managed the evaluation of hazardous air pollutant emissions from a petrochemical facility in support of a state air permitting amendment in Texas. This project involved a comprehensive assessment of the occupational and toxicology peer-reviewed and gray literature, evaluation of federal and state monitoring and modeling tools (e.g., NATA, RSEI), coordination and drafting of an extensive summary report, and the communication of toxicology and risk information to area residents during a public meeting coordinated by the state regulatory agency.

Investigated the proposed use of EPA TCE RfC as a short-term/immediate remediation action level; reviewed animal toxicology, epidemiology, and toxicokinetic data on reproductive and developmental effects of TCE, specifically as it related to fetal cardiac malformations. Worked with a state agency in EPA Region 4 to develop a health hazard-based and scientifically defensible level of concern for residential TCE exposures via vapor intrusion.

Provided toxicology support on a project in which regulatory modeled TCE air emission estimates associated with a facility's permitted TCE use raised concerns that potential residential exposures exceeded low-level health-based air standards developed by the state regulatory agency in EPA Region 10.

## Systematic Review and Evidenced-Based Toxicology

Managed a systematic review project on vanadium as a case study as part of an effort to develop and update a state agency's systematic review protocols in support of chemical risk assessment. From this review, experimental animal and epidemiology studies potentially relevant to human health risk assessment were screened using SysRev, with data extracted and evaluated systematically using study quality metrics based on EPA's HAWC.





Project manager on a large systematic review project for a state regulatory agency in which a comprehensive systematic map was created for the toxicology and epidemiology literature for 16 PFAS compounds. From this literature mapping database, experimental animal and epidemiology studies potentially relevant to human health risk assessment were screened, extracted, and evaluated systematically using a protocol and study quality metrics based on EPA's HAWC.

Applied systematic review concepts of internal, external, and construct validity to a comprehensive evaluation of the *in vitro* literature reporting relative potency (REP) values for dioxin-like PCBs using various human cell models and AhR pathway endpoints. Following a weight-of-evidence integration and decision framework, this effort resulted in the application of a study relevance/quality weighting scheme to the updated REP database for PCB126 to inform an updated TEF for the DL-PCB congener.

Developed a comparative assessment of *in vitro* critical appraisal tools (ToxRTool, SciRAP, EPA-OPPT's TSCA tool) using published data sets generated from human- and animal-cell models in support of a risk evaluation related to *in utero* exposures to trichloroethylene.

Conducted a risk-of-bias (RoB) assessment per the National Toxicology Program's Office of Health Assessment and Translation (NTP-OHAT) guidelines on the animal and human peer-reviewed studies that make up the database for the hypothesis that *in utero* exposure to TCE causes congenital heart defects.

Conducted systematic review of the relationship between sperm quality and pre- and perinatal dioxin exposures in human and animal studies. Used the NTP-OHAT's RoB Tool to evaluate epidemiology and *in vivo* studies. The resulting animal evidence base was integrated into a weighted, meta-regression analysis to characterize the doseresponse relationship in rats and to define a range of data-specific reference doses (RfDs).

Participated in evaluation for the improvement of the SciRAP *in vitro* critical appraisal tool, the product of a collaboration between the researchers at Stockholm University (Department of Environmental Science and Analytical Chemistry) and the Karolinska Institute (Institute of Environmental Medicine).

Evaluated a systematic critical appraisal tool developed by the Department of Defense (DoD) for evaluating noncancer *in vivo* data sets in support of developing an occupational exposure level (OEL) for TCE. The appraisal system was developed by the DoD as a fit-for-purpose approach for integrating elements of several available critical appraisal tools, which was reviewed by NASEM.

Participated in systematic review effort for the update of caffeine risk assessment evaluating consumption levels associated with adverse effects in humans. Helped develop several endpoint-specific systematic review protocols, and developed and applied DistillerSR screening forms to populate evidence base for endpoints of concern. Used the NTP's OHAT Risk of Bias Tool to evaluate epidemiology (experimental and observational) studies.

Developed a systematic map comparing the literature relevant to biomarkers associated with critical health endpoints related to the use of conventional and alternative tobacco products (including heat-not-burn and electronic cigarettes).

## Occupational Health

Managed a comprehensive toxicological evaluation of ortho-toluidine that led to the development of state of the science cancer risk-based exposure values recommended for updating federal occupational standards. This effort included a systematic evaluation of the relevant epidemiological database and utilized current human biomonitoring data and PBPK modeling to support the proposed alternative occupational exposure standards.

Managed and performed a Tier 3 risk assessment as provided in Missouri Risk-Based Corrective Action (MRBCA) guidance to evaluate potential worker exposures and health risks associated with VOC vapor intrusion at a manufacturing facility in the state. Utilized air monitoring data and job classification activities to characterize exposures and developed state-of-the-science toxicity factors to develop Tier 3 vapor intrusion screening levels protective of workers.





Coordinated and provided technical support for the development of strategies to reduce worker exposure to chemicals of potential concern at a primary magnesium production facility. Evaluated industrial hygiene and biomonitoring data for dioxin-like compounds and hexachlorobenzene relative to the general population, determining whether the measured levels posed a threat to worker health, and coordinated with a certified industrial hygienist to develop recommendations on improving occupational protocols and procedures.

Developed historical exposure reconstruction analysis of coke-oven workers exposed to the benzene-soluble fraction of total particulate matter present in coke-oven emissions. Exposure estimates were derived from regulatory and industrial personal and area monitoring efforts for each specific coke-oven job and were used to develop cumulative exposure and cancer risk estimates.

Conducted an extensive review of the reproductive and developmental toxicology and epidemiology literature of glycol ethers and their respective acetates identified in more than 100 products that represented potential exposure hazards to semiconductor facility employees. Occupational exposure was evaluated using historical industrial hygiene data, product purchasing data, and thousands of material safety data sheets (MSDSs). Hazard was assessed by comparing estimated exposures with toxicity criteria and regulatory exposure guidelines.

Performed a comprehensive toxicological review of various chemicals (VOCs, semi-volatile compounds, metals) identified in various industrial products and processes to which employees of a laminated plastics plant had potentially been exposed. In addition, employee symptoms and health complaints were compared with the toxicological profiles of each chemical of potential concern to focus the subsequent exposure assessment.

Assisted in biomonitoring analysis focused on exposures of former and current employees to dioxins and metals at copper smelter facilities. This work involved data analyses and interpretation regarding the levels of dioxin-like compounds in blood samples, the results of which were compared with the levels reported in other regional and national biomonitoring efforts to assess relative body burden.

## Food and Consumer Products

Provided support as a contract toxicologist for a large consumer products business conducting screening-level and comprehensive safety assessments (when warranted) on the constituents of a variety of grooming and beauty care products.

Managed and coordinated the firm's safety assessment support for a wide variety of cosmetic ingredients and raw materials for a cosmetics manufacturer. This role involved the refinement of a safety evaluation process reflective of the guidelines set by European Commission's Scientific Committee on Consumer Safety (SCCS), and the oversight and review of our team's safety assessors.

Conducted safety assessments on indoor and outdoor pest control products developed for international markets. The assessments were focused on potential maternal, fetal, and infant exposure scenarios and health outcomes.

Primary consulting toxicologist supporting multiple businesses in the development of product-level safety assessments for a series of nutrition products. This role involved review of draft product constituent assessments, and their integration into higher level assessments on the complete products for establishing consumer use recommendations.

Provided an internal assessment for a client on the potential human health risk associated with dermal exposures to an essential oil-based residential insecticide product, using QRA models published by the Research Institute for Fragrance Materials (RIFM) as well as EPA's residential pesticide exposure model.

Coordinated and managed subcontractor services providing toxicological guidance and expertise in support of an initiative by FDA's Center for Tobacco Products to develop risk assessments on unregulated tobacco products (e.g., electronic cigarettes). Conducted comprehensive reviews of the peer-reviewed literature and distilled into summary documents for various tobacco-related chemicals (nicotine, the tobacco-specific nitrosamines NNN and NNK, acrolein) and numerous tobacco product ingredients (flavor additive and enhancer compounds, and





complex essential oils). In addition, provided the client with dose-response modeling results on relevant studies of NNK carcinogenicity, and guidance on how to present such data in exposure-response arrays.

Managed the development of no-significant-risk levels (NSRLs) for beta-myrcene based on the 2010 NTP bioassay report, according to Proposition 65 regulatory guidance set forth by California's Office of Environmental Health Hazard Assessment (OEHHA).

Managed the development of an indoor air quality model tool kit for quantifying exposure and human health risk associated with trace volatile organic compounds present in the propellants used in consumer aerosols.

Researched and developed the safety sections of GRAS reports submitted to the FDA on non-caloric sweetener products.

Researched and published review manuscripts on the potential genotoxic and allergenic hazards related to consumption of highly purified, non-caloric sweetener products.

Served as an expert panel member for the GRAS evaluation of a high-purity, non-caloric, general-purpose sweetener.

Researched and drafted comments on the carcinogenicity or developmental/reproductive toxicity of pyrethroids (type 1 as a group and deltamethrin, respectively) for consideration by OEHHA Proposition 65 expert panels (DARTIC and CIC, respectively).

Conducted a comprehensive investigation into the mechanistic and empirical evidence supporting a potential association between certain food preservatives (sodium benzoate, parabens) with neurodegenerative disease.

Developed risk-based toxicity values for acrylamide based on extensive review of the literature and the most recent cancer bioassay data released by the National Toxicology Program.

Provided toxicology analysis for a human health risk assessment related to a detergent contaminant (nonylphenol ethoxylate) found at low levels in a product marketed for consumption. Integral to this assessment was the identification of a toxicological effects level used to develop a health benchmark and the calculation of exposure estimates, which are key determinants in decisions related to product shelf retention.

## Pharmaceuticals and Drug Development

Visited the campuses of several different CROs to conduct site monitoring of pre-clinical toxicology studies, including the dosing, handling and care of non-human primates, rabbits, and rodents. These were performed in support of investigational new drug (IND) application efforts for biological drug development. Responsibilities included evaluating CRO staff knowledge and adherence to proscribed treatment protocols, as well as general observations on laboratory conditions and laboratory feedback from regulatory agency inspections.

Provided toxicology and pharmacology expertise in support of a pre-IND application for a novel vaccine. Involved interpreting toxicology and pharmacology study data and facilitating sponsor and laboratory communication on study results and future study design.

Researched and developed a comprehensive summary of the toxicology data on an over-the-counter antihistamine pharmaceutical being considered for inclusion in a novel therapeutic formulation.

Conducted toxicological evaluations of chemical substances present or potentially present in vaccines, as well as derived safe levels for excipients, detergents, surfactants, and other chemicals utilized in the production or inactivation of vaccine products.

Designed and performed *in vitro* assays to evaluate the diverse G-protein coupled receptor-based binding and signaling profiles of several dopaminergic ligands, with a focus on atypical antipsychotic drugs and non-clinical development of novel Parkinson's Disease pharmacotherapies.





## **PUBLICATIONS**

Wikoff DS, **Urban JD**, Ring C, Britt J, Fitch S, Budinsky R, Haws LC. 2021. Development of a range of plausible non-cancer toxicity values for 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) based on effects on sperm count: Application of systematic review methods and quantitative integration of dose response using metaregression. Toxicol Sci 179(2):162-182; doi: 10.1093/toxsci/kfaa171.

**Urban JD**, Wikoff DS, Chappell GA, Harris C, Haws LC. 2020. Systematic evaluation of mechanistic data in assessing in utero exposures to trichloroethylene and development of congenital heart defects. Toxicol 436(Apr 30):152427; doi:10.1016/j.tox.2020.152427.

Wikoff D, **Urban JD**, Harvey S, Haws LC. 2018. Role of risk of bias in systematic review for chemical risk assessment: A case study in understanding the relationship between congenital heart defects and exposures to trichloroethylene. Int J Toxicol 37(2):125–143.

Wikoff D, Welsh BT, Henderson R, Brorby GP, Britt J, Myers E, Goldberger J,..., **Urban J**, et al. 2017. Systematic review of the potential adverse effects of caffeine consumption in healthy adults, pregnant women, adolescents, and children. Food Chem Toxicol 109(Pt1):585–648.

**Urban JD**, Carakostas MC, Taylor SL. 2015. Steviol glycoside safety: Are highly purified steviol glycoside sweeteners food allergens? Food Chem Toxicol 75:71–78.

Bunch AG, Perry CS, Abraham L, Wikoff DS, Tachovsky JA, Hixon JG, **Urban JD**, Harris MA, Haws LC. 2014. Evaluation of impact of shale gas operations in the Barnett Shale region on volatile organic compounds in air and potential human health risks. Sci Tot Environ 468–469:832–842.

**Urban JD**, Wikoff DS, Bunch AT, Harris MA, Haws LC. 2014. A review of background dioxin concentrations in urban/suburban and rural soils across the United States: Implications for site assessments and the establishment of soil cleanup levels. Sci Tot Environ 446–467:586–597.

Rowlands JC, Budinsky R, Gollapudi B, Black M, Wolfinger R, Cukovic D, Dombkowski A, Thompson C, **Urban JD**, Thomas R. 2013. A genomics-based analysis of relative potencies of dioxin-like compounds in primary rat hepatocytes. Toxicol Sci 136(2):595–604.

**Urban JD**, Carakostas MC, Brusick, DJ. 2013. Steviol glycoside safety: Is the genotoxicity database sufficient? Food Chem Toxicol 51:386–390.

Fowler JC, Bhattacharya S, **Urban JD**, Vaidehi N, Mailman RB. 2012. Receptor conformations involved in dopamine D2L receptor functional selectivity induced by selected transmembrane 5 serine mutations. Mol Pharmacol 81(6):820–831.

Thompson CM, Hixon JG, Proctor DM, Haws LC, Suh M, **Urban JD**, Harris MA. 2012. Assessment of genotoxic potential of Cr(VI) in the mouse duodenum: An in silico comparison with mutagenic and nonmutagenic carcinogens across tissues. Regul Toxicol Pharmacol 64(1):68–76.

**Urban JD**, Budinsky RA, Rowlands JC. 2012. An evaluation of single nucleotide polymorphisms in the human heat shock protein 90kDa alpha and beta isoforms. Drug Metab Pharmacokinet 27(2):268-278.

Rowlands JC, **Urban JD**, Wikoff DS, Budinsky RA. 2011. An evaluation of single nucleotide polymorphisms in the human aryl hydrocarbon receptor-interacting protein (AIP) gene. Drug Metab Pharmacokinet 26(4):431–439.

Tichomirowa MA, Bariler A, Daly AF, Jaffrain-Rea M-L, Ronchi CL, Yaneva M, **Urban JD**, et al. 2011. High prevalence of AIP gene mutations following focused screening in young patients with sporadic pituitary macroadenomas. Eur J Endocrinol 165(4):509–515.

**Urban JD**, Rowlands JC, Budinsky RA. 2011. Single nucleotide polymorphisms in the human aryl hydrocarbon receptor nuclear translocator (ARNT) gene. Drug Metab Pharmacokinet 26(6):637–645.





Tachovsky JA, **Urban JD**, Wikoff DS, Haws LC, Harris MA. 2010. Reduction of a large fish tissue analyte database: Identifying and assessing data specific to a remediation site for risk assessment application. Chemosphere 80(5):481–488.

**Urban J**, Tachovsky JA, Haws L, Wikoff Staskal D, Harris M. 2010. Response to Mugdan et al.'s comment on Urban et al., "Assessment of Human Health Risks Posed by Consumption of Fish from the Lower Passaic River, New Jersey." Sci Tot Environ 408(6):1468–1470.

**Urban JD**, Tachovsky JA, Haws LC, Staskal DF, Harris MA. 2010. Response to Buchanan et al.'s comment on Urban et al., "Assessment of Human Health Risks Posed by Consumption of Fish from the Lower Passaic River, New Jersey." Sci Tot Environ 408(8):2004–2007.

**Urban JD**, Tachovsky JA, Staskal DF, Haws LC, Harris MA. 2009. Assessment of human health risks posed by consumption of fish from the Lower Passaic River, New Jersey. Sci Tot Environ 408(2):209–24.

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Staskal DF, Scott LLF, Birnbaum LS, Williams ES, Haws LC, Luksemburg WJ, **Urban JD**, Nguyen LM, et al. 2008. Polybrominated diphenyl ethers in farm-raised and wild-caught catfish from southern Mississippi. Environ Sci Technol 42(17):6755–6761.

**Urban JD,** Clarke WP, von Zastrow M, Kobilka B, Nichols DE, Weinstein H, Javitch JA, Roth BL, et al. 2007. Functional selectivity and classical concepts of quantitative pharmacology (Perspective in Pharmacology). J Pharmacol Experimental Therapeut 320(1):1–13 [Journal Cover].

**Urban JD**, Vargas G, von Zastrow M, Mailman RB. 2007. Aripiprazole has functionally selective actions at D2 receptor-mediated signaling pathways. Neuropsychopharmacol 32(1):67–77.

Gay EA, **Urban JD**, Nichols DE, Oxford GS, Mailman RB. 2004. Functional selectivity of D2 receptor ligands in a Chinese hamster ovary hD2L cell line: Evidence for induction of ligand-specific receptor states. Molec Pharmacol 66(1):97–105.

#### **PROTOCOLS**

**Urban J**, Wikoff D, Haws L, Fitch S, Ring C, Thompson C, Suh M. 2018. Systematic review protocol: Systematic review and meta-regression to characterize the dose-response relationship between exposure to dioxin-like compounds during sensitive windows of development and reduced sperm count. Zenodo. http://doi.org/10.5281/zenodo.1636357.

Wikoff D, Doepker C, Welsh B, **Urban J**, Henderson R, Brorby G, Britt J, Harvey S, et al. 2015. Systematic review of the adverse cardiovascular effects of caffeine consumption in healthy adults, pregnant women, adolescents, and children. PROSPERO 2015:CRD42015026673. Available from http://www.crd.york.ac.uk/PROSPERO/display\_record.asp?ID=CRD42015026673

Wikoff D, Doepker C, Welsh B, **Urban J**, Henderson R, Britt J, Harvey S, Goldberger J, et al. 2015. Systematic review of the adverse bone and calcium balance effects of caffeine consumption in healthy adults, pregnant women, adolescents, and children. PROSPERO 2015:CRD42015026609 Available from <a href="http://www.crd.york.ac.uk/PROSPERO/display\_record.asp?ID=CRD42015026609">http://www.crd.york.ac.uk/PROSPERO/display\_record.asp?ID=CRD42015026609</a>

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Wikoff D, Doepker C, Welsh B, Harvey S, Goldberger J, Lieberman H, Myers E,..., **Urban J**, Weaver C. 2015. Systematic review of acute adverse effects of caffeine consumption in healthy adults, pregnant women, adolescents, and children. PROSPERO 2015:CRD42015026704 Available from <a href="http://www.crd.york.ac.uk/PROSPERO/display\_record.asp?ID=CRD42015026704">http://www.crd.york.ac.uk/PROSPERO/display\_record.asp?ID=CRD42015026704</a>

### INVITED LECTURES AND PRESENTATIONS

**Urban JD**. Systematic review and its role in risk assessment. Texas Commission on Environmental Quality - Environmental Trade Fair and Conference, Austin, TX, May 14, 2024.

**Urban JD**, Burkhalter K, Tachovsky JA, Thompson C, Haws LC, Harris MA. 2010. Evaluation of polychlorinated naphthalenes (PCNs) in Newark Bay sediment. Presented during the Dioxin-like Compounds in Urban Waterbodies Session at the 30<sup>th</sup> International Symposium on Halogenated Persistent Organic Pollutants, San Antonio, TX, September 14, 2010.

**Urban JD**, Mailman RB. Functional selectivity as a mechanism of action for newer atypical antipsychotic drugs. Presented at: Merck, West Point, PA, 2005.

### ABSTRACTS AND PRESENTATIONS

Lynn SG, Lea IA, **Urban J**, Borghoff SJ, Wikoff D, Fitch S, Perry C, Choksi N, et al. Development and application of systematic approach to inventory and interrogate thyroid hormone network information. Abstract #4357, Society of Toxicology 63<sup>rd</sup> Annual Meeting, Salt Lake City, UT, March 2024.

**Urban JD**, Covington TR, Fitch SE, Wikoff DS. Dioxin-like compounds in soils: A pilot survey updating background soil TEQ. Abstract #5147, Society of Toxicology 63rd Annual Meeting, Salt Lake City, UT, March 2024.

Lea I, Borghoff S, Wikoff W, Fitch S, **Urban J**, Perry C, Chappell G, Choksi N, et al. Case study application of a systematic approach to inventory and interrogate thyroid hormone network information. Abstract # P27, 12<sup>th</sup> Annual Meeting of the American Society for Cellular and Computational Toxicology, Silver Spring, MD, October 23-25, 2023.

Brown L, McMillan D, **Urban J**, Mihalchik A. A tiered-approach for assessing the safety of polymeric ingredients in cosmetics and personal care products. Abstract #3480-P605, Society of Toxicology 62<sup>nd</sup> Annual Meeting, Nashville, TN, March 19-23, 2023.

**Urban J**, Wikoff D, Haws L. Application of risk of bias for environmental epidemiology evidence characterization and integration in support of risk assessment: A case study evaluating the relationship between exposure to dioxin-like compounds (DLCs) and sperm count. Presented at the National Academy of Sciences, Engineering and Medicine's Workshops to Support EPA's Development of Human Health Assessments: Triangulation of Evidence in Environmental Epidemiology, Virtual, May 9 and 11, 2022.

Wikoff DS, Edwards S, Angrish M, Baumgartner P, Bever JB, Borghoff S, Chappell G,.., **Urban J**, et al. Application of systematic methods to characterize thyroid adverse outcome pathways (AOPs). Presented at the American Society for Cellular and Computational Toxicology 2021 Annual Meeting, Virtual, October 12-14, 2021.

**Urban JD**, Wikoff DS, Chappell GA, Haws LC. A systematic evaluation of the mechanistic data relevant to *in utero* exposures to trichloroethylene and the development of congenital heart defects. Presented at the Society of Risk Analysis 2020 Annual Meeting, Virtual, December 13-17, 2020.

**Urban JD**, Wikoff DS, Fitch S, Ring CL, Haws LC, Harris MA. An assessment of the relative potency of the dioxin-like polychlorinated biphenyl PCB126: Are the human *in vitro* studies sufficient? Presented at the 39<sup>th</sup> International Symposium on Halogenated Persistent Organic Pollutants, Kyoto, Japan, August 25-30, 2019.





**Urban JD**, Wikoff DS, Fitch S, Ring CL, Haws LC, Harris MA. An evaluation of the utility of human cell models for characterizing relative potency for dioxin-like compounds. Abstract #0948, presented at the IUTOX 15<sup>th</sup> International Congress of Toxicology (ICTXV), Honolulu, HI, July 15-18, 2019.

**Urban JD**, Wikoff DS, Haws LC. Three-tiered approach to integrating evidence streams assessing gestational trichloroethylene exposure and congenital heart defects (TCE-CHD). Presented at the National Academy of Sciences, Engineering and Medicine Workshop: Evidence Integration in Chemical Assessments: Challenges Faced in Developing and Communicating Human Health Effect Conclusions, Washington DC, June 3-4, 2019.

**Urban JD**, Wikoff D, Suh M, Britt J, Fitch S, Chappell G, Haws LC. Comparison of NTP OHAT and USEPA TSCA study quality criteria - Trichloroethylene (TCE) and congenital heart defects (CHDs) as a case study. Abstract #2801-P305, presented at Society of Toxicology 58<sup>th</sup> Annual Meeting, Baltimore, MD, March 10-14, 2019.

Ring CL, **Urban JD**, Wikoff D, Thompson CM, Budinsky RA, Haws LC. Application of systematic review and quantitative evidence integration methods to support risk assessment: Characterization of the dose-response relationship between exposure to dioxin-like compounds (DLC) and sperm count. Abstract #3492-P288, presented at Society of Toxicology 58<sup>th</sup> Annual Meeting, Baltimore, MD, March 10-14, 2019.

Wikoff D, **Urban J**, Chappell G, Haws LC. Application of mechanistic data quality criteria in assessment of the relationship between congenital heart defects and TCE exposure – A case study. Presented at the National Academy of Sciences, Engineering and Medicine Workshop: Strategies and Tools for Conducting Systematic Reviews of Mechanistic Data to Support Chemical Assessments, Washington DC, December 10-11, 2018.

Wikoff D, Ring CL, Thompson C, **Urban J**, Budinsky RA, Haws LC. Characterization of the dose-response relationship for TCDD and changes in sperm concentration in rats using meta-regression: A feasibility assessment of quantitative evidence integration techniques. Presented at the 38<sup>th</sup> International Symposium on Halogenated Persistent Organic Pollutants, Krakow, Poland, August 26-31, 2018.

**Urban JD**, Harvey S, Wikoff D, Haws LC. Assessment of study quality (risk of bias) in understanding the relationship between congenital heart defects (CHDs) and exposures to trichloroethylene (TCE). Abstract #2842-P365, presented at Society of Toxicology 57<sup>th</sup> Annual Meeting, San Antonio, TX, March 11-15, 2018.

Borghoff SJ, Wikoff D, **Urban JD**, Rager JE. A systematic approach to identify plausible mode-of-actions (MOAs) for an increased incidence of lung tumors in mice with chronic exposure to 4-methylimidazole (4-MEI). Presented at Society of Toxicology 57<sup>th</sup> Annual Meeting, San Antonio, TX, March 11-15, 2018.

**Urban JD**, Thompson CM, Plunkett LM, Perry CS, Haws LC. A state of the science copper reference dose for soil remediation. Presented at Society of Toxicology 54<sup>th</sup> Annual Meeting, San Diego, CA, March 22–26, 2015.

**Urban JD**, Perry C, Wikoff D, Abraham L, Harris MA. Lower Passaic River RM0-8: An alternative human health risk assessment. Abstract # 272, presented at the 8<sup>th</sup> International Conference on Remediation and Management of Contaminated Sediments, New Orleans, LA, January 12-15, 2015.

Abraham L, Harris MA, Perry C, **Urban JD**, Wikoff D, Kinnell JC, Bingham M, Hickman S. Lower Passaic River RM0-8: An alternative preliminary remediation goal. Abstract #187, resented at the 8<sup>th</sup> International Conference on Remediation and Management of Contaminated Sediments, New Orleans, LA, January 12-15, 2015

**Urban JD**, Doepker CL, Cuellar-Kingston N, van de Ligt J, Carakostas M. Do highly purified steviol glycoside sweeteners cause food allergies? Presented at Society of Toxicology 53<sup>rd</sup> Annual Meeting, Phoenix, AZ, March 23–27, 2014.

**Urban JD**, Thompson CM, Deskin R, Waite M, Haws LC. Development of an oral cancer slope factor for acrylamide based on tumors relevant to humans. Abstract #2221-419, presented at Society of Toxicology 52nd Annual Meeting, San Antonio, TX March 10–14, 2013.

**Urban J**, Rowlands JC, Budinsky R, Dombkowski A, Thompson CM, Thomas R. A genomics-based benchmark dose analyses of relative potencies of dioxin like compounds in primary rat hepatocytes. Abstract #1726,





presented at Society of Toxicology 51st Annual Meeting. San Francisco, CA, March 11–15, 2012 (*Top 10 abstract in SOT Risk Assessment Specialty Section*)

Perry C, Tachovsky JA, Ke M, **Urban J**, Haws L. Natural gas exploration and production in the Barnett Shale: Assessment of exposures to volatile organic compounds (VOCs). Abstract #108, presented at Society of Toxicology 51st Annual Meeting, San Francisco, CA, March 11–15, 2012.

Rowlands JC, Budinsky R, Gollapudi B, Cukovic D, Salagrama S, Dombkowski A, **Urban J**, Thompson C, Thomas R. An evaluation of relative changes in genomic gene expression in primary rat hepatocytes exposed to TCDD, 4-PeCDF, and TCDF. Presented at the 31st International Symposium on Halogenated Persistent Organic Pollutants., Brussels, Belgium, August 21–25, 2011.

Rowlands JC, **Urban J**, Wikoff DS, Budinsky R. The presence and estimated functional effect of single nucleotide polymorphisms at the AIP, ARNT, HSP90AA1, and HSP90AB1 loci in the human population. Presented at the 31st International Symposium on Halogenated Persistent Organic Pollutants, Brussels, Belgium, August 21–25, 2011.

Thomas RS, Rowlands JC, Budinsky RA, Thompson CM, **Urban JD**, Dombkowski A. Genomic approaches for relative potency assessment. Presented at the 31st International Symposium on Halogenated Persistent Organic Pollutants, Brussels, Belgium, August 21–25, 2011.

Budinsky R, **Urban J**, Rowlands JC. An evaluation of single nucleotide polymorphisms in the human aryl hydrocarbon receptor nuclear translocator gene. Presented at Society of Toxicology 50th Annual Meeting,. Washington, DC, March 6–10, 2011.

Fitzgerald L, Burkhalter B, **Urban J**, Staskal D, Harris M, Haws L. VOC serum levels in the general U.S. population: An analysis of the 2003-2004 NHANES dataset. Presented at Society of Toxicology 50th Annual Meeting, Washington, DC, March 6–10, 2011.

**Urban J**, Fitzgerald L, Burkhalter B, Staskal D, Harris M, Haws L. BTEX serum levels in the general U.S. population: An analysis of 2003-2004 NHANES dataset. Presented at Society of Toxicology 50th Annual Meeting, Washington, DC, March 6–10, 2011.

Haws L, Tachovsky JA, Staskal-Wikoff D, Aylward L, Burkhalter B, **Urban J**, Simon T, Harris M. 2010. An evaluation of the influence of different soil cleanup levels on the concentration of dioxin-like compounds in human serum. Presented at the 30th International Symposium on Halogenated Persistent Organic Pollutants, San Antonio, TX, September 12–17, 2010.

**Urban J**, Burkhalter B, Tachovsky JA, Haws L, Harris M. Evaluation of polychlorinated naphthalenes (PCNs) in Newark Bay sediment. Presented at the 30th International Symposium on Halogenated Persistent Organic Pollutants, San Antonio, TX, September 12–17, 2010.

Harris M, Tachovsky JA, Staskal-Wikoff D, Simon T, Burkhalter B, **Urban J**, Haws L. Assessment of the impact of various soil cleanup levels on serum concentrations of dioxin-like compounds in humans. Presented at Society of Toxicology 49th Annual Meeting, Salt Lake City, UT, March 7–11, 2010.

Tachovsky A, Staskal D, **Urban J**, Harris MA, Haws L. Assessment of environmental data collected in a community with numerous petroleum refining and petrochemical facilities. Presented at Society of Toxicology 49th Annual Meeting, Salt Lake City, UT, March 7–11, 2010.

**Urban JD**, Tachovsky JA, Staskal DF, Haws LC, Harris MA. Human health risk assessment of consumption of fish from the Lower Passaic River. Presented at Society of Toxicology 48<sup>th</sup> Annual Meeting, Baltimore, MD, March 15–19, 2009.

**Urban JD**, Haws LC, Staskal DF, Scott LF, Scott PS, Tachovsky AT, Unice KM, Harris MA. A framework for evaluating serum dioxin data derived from biomonitoring studies. Presented at the 28th International Symposium on Halogenated Persistent Organic Pollutants, Birmingham, England, August 17–22, 2008.





**Urban JD**, Haws LC, Scott LF, Scott PS, Staskal DF, Tachovsky AT, Unice KM, Harris MA. A framework for evaluating serum dioxin data derived from biomonitoring studies. Abstract #1198–637, presented Society of Toxicology 47<sup>th</sup> Annual Meeting, Seattle, WA, March 16–20, 2008.

**Urban JD**, Thornley K, Wightman RW, Mailman RB. Pharmacological characterization of the N27-D2L cell line: Assessment as a viable cell model for investigating D2L receptor dopaminergic-coupled functions. Abstract #1058–231, presented at Society of Toxicology 46<sup>th</sup> Annual Meeting, Charlotte, NC, March 25–29, 2007.

Fuhrmann K, **Urban J**, Mailman R. TM5 serines effect on D<sub>2L</sub> dopamine receptor partial agonist pharmacology: Elucidating functional selectivity. Presented for the 2006 Summer Undergraduate Research Experience, University of North Carolina, Chapel Hill, NC, July 26, 2006.

**Urban JD,** Jin J, Mailman RB. N27 dopaminergic cell line: A useful model for studying the mechanisms of action of functionally selective dopaminergic compounds. Abstract #1374, presented at Society of Toxicology 45<sup>th</sup> Annual Meeting, San Diego, CA, March 5–9, 2006.

**Urban JD,** Mailman RB. Characterization of the N27 dopaminergic cell line as a model for elucidating the actions of functionally selective dopaminergic ligands. Abstract #32.21, presented at the 35<sup>th</sup> Annual Neuroscience Meeting, Washington, DC, November 12–16, 2005.

**Urban JD,** Mailman RB. Functional selectivity as a mechanism of action for newer atypical antipsychotic drugs. Presented at: Merck, West Point, Pennsylvania, USA, 2005.

**Urban JD**, Gay, Mailman RB. Functional selectivity as a mechanism of action of newer atypical antipsychotic drugs. Abstract #163.4, presented at the 34<sup>th</sup> Annual Neuroscience Meeting, San Diego, CA, October 23–27, 2004.

**Urban JD**, Gay EA, Mailman RB. 2004. Decreased neurological side-effects with aripiprazole: A result of functional selectivity of the D2 receptor? Abstract #313, presented at Society of Toxicology 43<sup>rd</sup> Annual Meeting, Baltimore, MD, March 21–25, 2004.

### SELECTED CONTINUING EDUCATION

Harnessing Toxicology in Pregnancy: Traditional and Novel Approaches to Placental Toxicology Research. Society of Toxicology. March 10, 2024.

Weight of Evidence Analysis and Problem Formulation for Chemical Risk Assessment: Fundamental Principles and Application through Case Examples. Society of Toxicology. March 10, 2024.

Embryology and Developmental Toxicity Testing. Society of Toxicology. March 13, 2016.

Human Health Risk Assessment: A Case Study Application of Principles. Society of Toxicology. March 13, 2016.

Adverse Outcome Pathway (AOP) Development and Evaluation. Society of Toxicology. March 13, 2016.

Gonadal Development, Function, and Toxicology. Society of Toxicology. March 10, 2013.

Approval of Biosimilar Monoclonal Antibodies: Scientific, Regulatory and Legal Challenges. Society of Toxicology. March 10, 2013.

Best Practices for Developing, Characterizing, and Applying Physiologically Based Pharmacokinetic Models in Risk Assessment. Society of Toxicology. March 6, 2011.

Beyond Science and Decisions: From Problem Formulation to Dose-Response. Workshop I. Alliance for Risk Assessment. March 16-18, 2010.

Epidemiology for Toxicologists: Introduction. Society of Toxicology. March 16, 2008.





Dose Response Modeling for Occupational and Environmental Risk Assessment. Society of Toxicology. March 16, 2008.

Allergy and Allergic Disease: A Primer for Toxicologists. Society of Toxicology. March 25, 2007.

Neuropathology for the Toxicologist. Society of Toxicology. March 5, 2006.

Essentials of Metal Toxicology. Society of Toxicology. March 5, 2006

