Jonathan J. Heywood, MPH
Senior Toxicologist

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Academic and Professional Profile

Mr. Jonathan Heywood is a toxicologist and risk assessor with seven years of experience examining potential human health effects related to environmental contaminants, consumer products, occupational exposures, and airborne hazards. He has six years of scientific consulting experience in toxicology, exposure and risk assessment, and industrial hygiene. Health effects associated with electronic nicotine delivery systems (ENDS, also known as e-cigarettes or vapes) are a significant recent focus of Mr. Heywood's work, along with the beneficial and adverse effects of various kratom products. His ENDS-related work specifically focuses on the interplay between risk mitigation (relative to nicotine delivery via conventional cigarettes) and potential risks associated with exposure to degradation products found in ENDS aerosols due to e-liquid heating during device use. Of particular interest are HPHCs and degradation products including methylglyoxal, diacetyl, glycidol, and various aldehydes. Specific to kratom, his work explores the beneficial and adverse effects of kratom and its key alkaloids (mitragynine and related stereoisomers, 7-hydroxymitragynine) within a reduced-risk framework relative to the risks of traditional opioid use. Beyond ENDS, Mr. Heywood has significant recent experience in completing risk assessments of the carcinogenicity of *n*-nitrosamine pharmaceutical contamination, along with experience conducting risk assessments for human exposure to asbestos, talc, radionuclides, benzene, diesel, creosote, food contaminants, BTEX compounds, disinfection products, PFAS, 4-aminobiphenyl, paraquat, glyphosate, 1,1-difluoroethane, mitragynine, noise, and SARs-CoV-2. In addition to his technical expertise, Mr. Heywood has significant experience with project management, business real estate transactions, business development and new client identification, and staff recruiting, training, and supervision. He holds a master of public health (MPH) in environmental and occupational health from the University of Colorado and a bachelor of science from the University of Nevada, Reno.

Education and Degrees Earned

- Master's of Public Health, Environmental and Occupational Health, University of Colorado, 2018
- Bachelor's of Science, Wildlife Ecology and Conservation, University of Nevada, Reno, 2016

Experience Summary (Professional Career)

Paustenbach and Associates
Senior Toxicologist
Boulder, Colorado
February 2021 – Present

- Consultant in toxicology, occupational health, industrial hygiene, exposure and risk assessment, state of the art, and safety.
- Currently focused on nitrosamine contamination in pharmaceuticals, e-cigarette and vaping-associated health risks, asbestos, benzene, radionuclides, consumer products toxicology, and environmental and occupational toxicology (various topics).
- Involved in litigation work, interpreting toxicological studies, conducting exposure assessments, assessing mathematical models for dose-response curves, and characterizing risks posed by chemicals in environmental and occupational scenarios.
- Skilled project manager for various litigation and non-litigation clients, including managing more than $2 million/year in revenue.

Cardno ChemRisk
Senior Associate Toxicologist
Boulder, Colorado
June 2018 – February 2021

- Consultant in exposure assessment, toxicology, industrial hygiene, state of the art, and risk mitigation.
- Experience with occupational and non-occupational exposures to e-cigarette (vaping) substituents; asbestos; talc; benzene; diesel exhaust, fumes, and soot; creosote; diacetyl; ethylene oxide; peracetic acid; herbicides; silica; and various components of personal care products including cosmetics, shampoos, and sunscreens.
- Project management experience for various asbestos, state of the art, and person most knowledgeable clients, along with extensive litigation support experience.
- Contribution to ongoing consulting related to risk mitigation policies associated with occupational environments and Covid-19.

National Environmental Health Association
Intern
Denver, Colorado
May 2017 – May 2018

- Conducted an assessment of the utility of CDC's Model Aquatic Health Code (MAHC) on improving the safety of public recreational water environments such as pools, spas, and waterparks.
- Developed and implemented a dual approach quantitative/qualitative study to assess the

influence of the MAHC on health outcomes and analyzed subsequent data.

Colorado School of Public Health
Graduate Student Researcher
Aurora, Colorado
November 2016 – August 2017

- Was part of a research group that examined noise and air pollution (primarily BTEX compounds) produced from unconventional oil and gas development (fracking) in close proximity to residential communities.
- Examined the literature regarding health effects associated with noise and pollution exposures at measured levels.
- Communicated findings with community members and other stakeholders.

Key Projects (Partial List)

1. **Toxicological assessment of kratom, mitragynine, and 7-hydroxymitragynine.** The plant product kratom (*Mitragyna speciosa* Korth) has been used for centuries in Southeast Asia and gained popularity in the United States over the past two decades. Work focused on both general toxicological and process advice for industry players, including kratom processors and distributors, along with litigation support for claims related to acute mitragynine toxicity. Included development of prospective studies to better understand the *in vitro*, *in vivo*, and human toxicology of kratom alkaloids and marketed products. Examined the literature to determine evidence for toxic effect thresholds and potential derivation of acceptable intake (AI) levels for alkaloids and inform human exposure and risk assessments based on product alkaloid concentrations (2023-2024).

2. ***N*-Nitrosamines in pharmaceuticals.** Claims associated with n-nitrosodimethylamine (NDMA) and n-nitrosodiethylamine (NDEA) contamination in angiotensin II receptor blockers (ARBs), histamine 2 blockers (H2 blockers), and other drug types, along with potential n-nitrosamine formation during production of active pharmaceutical ingredients (APIs). Examined the literature to determine the suitability of FDA's existing acceptable intake (AI) levels for n-nitrosamines in pharmaceuticals relative to potential carcinogenic risks among users. Also examined approaches for detection, quantification, and regulation of novel n-nitrosamines generated during pharmaceutical production, including the appropriateness of quantitative structure-activity relationship (QSAR) models and other new assessment methods (NAMs) (2022-2024).

3. **Radiological assessment of pipeline industry-associated exposures.** Claims related to exposure of pipeline employees to naturally occurring radioactive material (NORM) and technologically enhanced naturally occurring radioactive material (TENORM) during pipeline maintenance and cleaning activities. Performed an exposure and risk assessment based on work-activity-specific potential for exposure to radionuclides including lead-

210, polonium-210, radon-222, and radium-226 to derive total effective dose equivalents (TEDEs) relative to the OSHA annual occupational dose limit for whole-body exposure of 5 rem (2022-2023).

4. **Assessment of the asbestos hazard of laboratory products.** Claims related to potential chrysotile asbestos exposure during use of laboratory products including gloves, mittens, tongs, pads/mats, fume hoods, and wire gauze. Performed quantitative exposure and risk assessments to elucidate health risks relative to potential cumulative chrysotile dose (2021-2024).

5. **Evaluation of the toxicological risks of e-cigarettes.** Claims related to respiratory irritation (e.g., exacerbation of asthma) associated with typical use of closed-system e-cigarettes (vapes). Potential claims of carcinogenic effects were also evaluated. Performed comprehensive literature reviews related to the primary constituents of e-cigarette liquids (nicotine, glycerol, propylene glycol), flavorants (e.g., diacetyl, vanillin), heat-associated degradation products (e.g., formaldehyde, acetaldehyde, acrolein), and various other compounds detected in e-cigarette aerosols (e.g., methylglyoxal, glycidol) (2021-2024).

6. **Evaluation of occupational exposures to trace benzene.** Claims related to potential exposure to benzene among manufacturing, petroleum industry, transport, and marine industry workers. Performed risk assessments incorporating data on products used, potential trace benzene levels in these products (if any), and potential for exposure-related health effects (2021-2024).

7. **Evaluation of SARs-CoV-2 (the virus that causes COVID-19) transmission in occupational settings.** Across multiple projects, evaluated the potential for transmission of SARs-CoV-2 in workplace settings and potential risk of infection and subsequent development of COVID-19. Claims related to both infections caused by workplace attendance (including fatal cases) and potential insurance losses associated with facility closures. Included site assessments at large-scale manufacturing facilities (2021-2023).

8. **Assessment of occupational and non-occupational asbestos exposures and potential for such exposures to yield health effects.** Various claims associated with exposure to allegedly asbestos-containing products including insulation, transite, gaskets, packing, clutches, brakes, and electrical components, among other materials. Assisted with exposure assessment to examine the potential for given product(s) to yield health effects at exposure levels likely experienced by users and/or bystanders (2018-2021).

9. **Evaluation of exposures associated with railroad environments and potential for health effects following work in such environments.** Claims associated with exposures in rail yard and track/road environments experienced by individuals in various railroad trades. Assisted with assessment of exposure to asbestos, diesel and its substituents,

creosote, benzene, herbicides, and silica, among other compounds, and potential for likely exposure levels to yield disease (2019-2021).

10. **Examination of non-occupational talc exposures and potential for development of exposure-associated health effects.** Claims associated with non-occupational use of talc for cosmetic and/or hygiene purposes were examined. Literature examining exposure from simulated scenarios was used to inform opinions regarding potential for exposure to cause alleged health outcomes (2018-2021).

11. **Analysis of various e-cigarette substituents for potential health effects at exposure levels commonly associated with vaping.** Various e-cigarette flavoring components were examined for toxicological risk. Where minimal data was available for given compound(s), QSAR was used to approximate toxicological potential (2019-2021).

12. **Health assessment of a community influenced by substantial transportation development.** Assisted with development of a health assessment to be conducted in a community where a large-scale transportation development was taking place. The assessment is ongoing and aims to quantify negative health effects associated with transportation development and propose mitigation strategies to be implemented by state and local health organizations (2020-2021).

13. **Examination of the toxicological risks posed by prior cargoes in vessels transporting food-grade products.** Quantified the risks of various prior cargoes in trans-oceanic shipping containers subsequently used to transport food products. Assisted with literature review and, where necessary, QSAR examination of prior cargoes for potential toxicological risks, and compared likely exposure levels from vessel contamination to U.S. and internationally published exposure guidelines (2020).

14. **Analysis of the efficacy and health risks of EPA List N disinfectants for use to mitigate the spread of Covid-19.** Performed a preliminary analysis of potential human health risks associated with routine use of disinfectants incorporated on EPA List N relative to published guidelines for use magnitude and information concerning health risks (2021).

15. **Evaluation of the ecotoxicological risks posed by a client's products relative to contemporary state of the science information for product substituents.** Based on historical corporate records, compared client knowledge of the ecotoxicological risks posed by compounds incorporated in client products to contemporary state of the science regarding such compounds. Allegations of client disregard for contemporary scientific knowledge at time of production were compared to the broader literature (2018).

Peer Reviewed Publications

1. Dennis Paustenbach, David Brew, Sabina Ligas, and **Jonathan Heywood.** 2021. A critical review of the 2020 EPA risk assessment for chrysotile and its many shortcomings. Critical Reviews in Toxicology 51(6): 509-539.
2. Dennis J. Paustenbach, Sarah E. Brown, **Jonathan J. Heywood,** Melinda T. Donnell, and David L. Eaton. 2024. Risk characterization of N-nitrosodimethylamine in pharmaceuticals. Food and Chemical Toxicology 186:1114498.
3. **Jonathan J. Heywood,** Sarah E. Smallets, and Dennis J. Paustenbach. 2024. Beneficial and Adverse Health Effects of Kratom: A Review of the Literature. Submitted to Food and Chemical Toxicology.
4. **Jonathan Heywood,** Grayson Abele, Sarah Smallets, Sydney Litvin, Blake Langenbach, and Dennis Paustenbach. Composition of E-Cigarette Aerosols: A Review and Commentary. To be submitted to Chemical Research in Toxicology.

Non-Peer Reviewed Publications

1. Dennis Paustenbach and select staff of Paustenbach and Associates. Comments to FDA, RE: Docket No. FDA-2023-N-1585 – Identification, Assessment, and Control of Nitrosamine Drug Substance-Related Impurities in Human Drug Products; Establishment of a Public Docket; Request for Comments. Submitted to FDA on July 3, 2023.

Poster Presentations

1. Dennis J. Paustenbach, Grayson R. Abele, **Jonathan J. Heywood,** and Melinda T. Donnell. A Methodology for Estimating 4-ABP Dermal Intake via Contaminated Consumer Products. Society of Toxicology (SOT) Annual Conference, March 27-31, 2022, San Diego, CA.
2. Sara Smallets, **Jonathan Heywood,** Blake Langenbach, Sydney Litvin, Maia Hilsabeck, and Dennis Paustenbach. Toxicology of Kratom (Mitragyna speciosa): A Review. Society of Toxicology (SOT) Annual conference, March 10-14, 2024, Salt Lake City, UT.

Professional Honors/Awards

- Deans List, University of Nevada, Reno, 2014-2016
- National Science Foundation EPSCoR UROP – 2015-2016 Annual Scholarship

Membership in Professional Societies

- Society of Toxicology (associate member)