THE EXPERTS
Robson Forensic

MICHAEL J. WHITEKUS, PhD, DABT
Toxicology and Drug Safety Expert

SUMMARY

Dr. Whitekus is a board certified toxicologist, with 25+ years of experience, who regularly performs causation analyses on alcohol, drugs, chemicals, inhaled particles/gases, pesticides, solvents, metals, and environmental contaminants.

PROFESSIONAL EXPERIENCE

2014 to present **Robson Forensic, Inc.**
Associate
Provide scientific and technical investigations, analysis, reports, and testimony toward the resolution of commercial and personal injury litigation of toxicology and human health assessments involving alcohol, prescription and recreational drugs, drugs of abuse, chemicals, toxicants, solvents, pesticides, metals, mold, food allergens, cosmetic products, environmental and occupational agents, related issues, and failure analysis.

2008 to 2011 **Pfizer Inc.**, Groton, CT
Drug Safety Team Lead, Toxicology

- Worked on cross functional drug development teams in matrix environment and provide leadership critical for drug safety evaluation and de-risking strategies
- Designed drug safety programs and studies consistent with ICH/FDA guidelines and under GLP/GMP requirements
- Directed the initiation, execution and reporting of drug safety studies
- Provided scientific and operational oversight on ~80 drug safety studies which included interaction with drug safety team lead, protocol generation, oversight of ~2-10 project personnel, execution of project, interpretation of data, written discussion of safety findings and drug safety report generation
- Oversaw and participated in cross-departmental activities for CNS drug safety program
- Presented/interpreted results of drug safety studies to program teams with go/no go decision
- Participated in monthly training meetings on regulatory, toxicology, and drug safety issues
- Evaluated toxicokinetic reports
- Authored toxicology reports and contributed to pharmacology and toxicology sections of investigational new drug applications (INDs) and new drug applications (NDAs)
- Invited participant and reviewer of Pfizer's toxicology operational reorganization
- Participated on Lyrica project team. Toxicological Sciences 128(1), 42-56 (2012)
- Received 6 performance awards for scientific excellence, problem solving abilities and committee involvement

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2005 to 2008 **BioReliance Corporation**, Rockville, MD
Laboratory Director, Toxicology

- Provided scientific and operational oversight on ~120 drug safety studies which included interaction with client, protocol generation, oversight of 2-15 project personnel, interpretation of study results, discussion of any findings, and generation of drug safety report
- Reviewed outsourced toxicokinetic reports
- Provided toxicology advice to clients
- Created two seminars (1 hour each) on carcinogenicity testing strategies at BioReliance and presented these at workshops around the country along with new scientific and regulatory developments
- Represented BioReliance during FDA site inspections and provided written responses
- Updated upper management via senior staff meetings on drug safety program progress
- Institutional Animal Care and Use Committee (IACUC) scientific representative
- Evaluated laboratories for compliance with internal SOPs and government regulations
- Responsible for overseeing work of report writers, study technicians, chemists, pathologists, and outside company contractors. Oversaw work of 15 people

2000 to 2005 **University of California Los Angeles**, Los Angeles, CA
Assistant Researcher/Post-Doctoral Researcher
Clinical Immunology and Allergy, UCLA School of Medicine
Emphasis: Inhalation Toxicology, Diesel Exhaust Particles, Allergy, Markers of Oxidative Stress, and Immunotherapy

- Examined the role of oxidative stress as a potential marker of adverse health effects induced by diesel particulate matter
- Responsible for study design, procurement and breeding of mice, inhalation treatment, dissection, measurement of *in vitro* immunological endpoints, data analysis, data presentation and publication of results
- Journal Expert Peer Reviewer: Journals refereed included Clinical Immunology, Toxicological Sciences, Toxicology and Applied Pharmacology, Environmental Toxicology and Pharmacology
- Invited to be on Toxicological Sciences editorial board in 2005
- Oversaw breeding and genotyping of a knock-out mouse colony
- Promoted to assistant researcher after ~3 years due to quality of work
- Publication: J. Immunol. 168:2560-2567, 2002

1995 to 2000 **Wayne State University**, Detroit, MI
Ph.D. Degree, Institute of Chemical Toxicology

- Hypothesis: Mercury causes autoimmune disease by attenuating CD95-mediated apoptosis
- Mechanistically explored how mercury attenuates CD95-mediated apoptosis using numerous in vitro assays (western blot, fluorometric, colorimetric, and flow cytometry) on Jurkat and U-937 cell lines and human primary T cells
- Selected Publications: J. Immunol. 162:7162-7170, 1999; Toxicol Appl Pharmacol.190 (2):146-56, 2003

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1995 **Parke-Davis Pharmaceutical Research Division**, Ann Arbor, MI
Assistant Scientist, Genetic Toxicology Department
- Evaluated the ability of drugs to cause DNA damage to cells
- Conducted *in vitro* micronucleus experiments and evaluated results microscopically
- Assisted in the maintenance of cell lines

1993 to 1994 **MPI,** Mattawan, MI
Metabolism and Bioanalytical Coordinator
- Developed HPLC methods and quantitated drug and metabolite levels in animal plasma samples from drug safety studies
- Supervised several BS chemists in HPLC lab

1991 to 1993 **Eastern Michigan University**, Ypsilanti, MI
Master of Science Degree
- Thesis: Isolated RNA and used RT-PCR to develop a unique in vitro PCR assay system to evaluate testicular toxins
- Evaluated HSP 27 and HSP 70 as potential markers of testicular toxicity

EDUCATION

Ph.D., Molecular and Cellular Toxicology, Wayne State University, Institute of Chemical Toxicology, Detroit, MI, 2000
M.S., Chemistry (Emphasis in Toxicology) Eastern Michigan University, Ypsilanti, MI, 1993
B.S., Chemistry (Math minor), Eastern Michigan University, Ypsilanti, MI, 1991
Michigan State Secondary Teacher Certification (Chemistry/Math) Grades 7-12

Continuing Education
Oral Fluid II webinar organized by the Society of Forensic Toxicology, December 2020
Cannabis Impaired Driving Continuing Education webinar course organized by the Society of Forensic Toxicology, September 2020
Method Development, Continuing Education webinar course organized by the Society of Forensic Toxicology, September 2020
Oral Fluid webinar organized by the Society of Forensic Toxicology, July 2020
Current Trends in Forensic Toxicology (online webinar), June 2020
Achieving the Standard for Analytical Scope & Sensitivity Testing in Impaired Driving using Laminar Flow Tandem Mass Spec, (webinar), PerkinElmer, April 2020
Recommended Specimens, Scope, Cutoffs, and Strategies for DUI/D Testing & the Impact of Stop Limit Tests, Continuing Education course organized by the Society of Forensic Toxicology, San Antonio, TX, October 2019
Best Practices for Investigation of Overdose Deaths, Continuing Education course organized by the Society of Forensic Toxicology, San Antonio, TX, October 2019
Application of QTOF Techniques: Approaches and Workflows, Continuing Education course organized by the Society of Forensic Toxicology, San Antonio, TX, October 2019

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ANAB ISO 17025: 2017 & ABFT Accreditation - Bridging the Gaps, Continuing Education course organized by the Society of Forensic Toxicology, San Antonio, TX, October 2019
Forensic Toxicology Board Certification Preparation Course, Organized by The Center for Forensic Science Research and Education, Webinar, Completed September 2019
Legal Cannabis: Medical, Toxicological, and Public Health Implications, Workshop organized by the American College of Medical Toxicology, San Francisco, CA, April 2019
The National Transportation Safety Board (NTSB): Understanding and Preventing Impairment in Transportation, Workshop organized by the American Academy of Forensic Sciences, Baltimore, MD, February 2019
Pathology and Drug Related Deaths, Organized by The Center for Forensic Science Research and Education, Webinar, November 2018
Novel Psychoactive Substances Symposium, Organized by The Center for Forensic Science Research and Education, Philadelphia, PA, November 2018
Weaving Together the Toxicologist and the Drug Recognition Expert, Continuing Education course organized by the Society of Forensic Toxicology, Minneapolis, MN, October 2018
The Real C.S.I. Miami – A Collaborative Approach to Death Investigation with an Emphasis on Investigative Postmortem Toxicology, Continuing education course organized by the Society of Forensic Toxicology, Minneapolis, MN, October 2018
DUID and Oral Fluid Workshop, Organized by the Society of Forensic Toxicologists, Inc., Albany, NY, June 2018
Virtual/Online Symposium: Current Trends in Forensic Toxicology, Forensic Science Education, May 2018
Postmortem Interpretive Toxicology; Organized by The Center for Forensic Science Research & Education; Philadelphia, PA, April 2018
Opioids, Toxicology, and the Law: Medical-Legal Aspects of the Opioid Epidemic; Organized by the American College of Medical Toxicology and the Society of Forensic Toxicologists; Philadelphia, PA, December 2017
Forensic Pharmacology, organized by the Center for Forensic Science Research & Education, June 2017
Certified as a Diplomate of the American Board of Toxicology, November 2016
Webinar Topic: Marijuana Legalization: Trends & Hot Topics, Occupational Health and Safety, February 2016
Marijuana Summit, Governor's Council on Alcoholism and Drug Abuse, Cherry Hill, NJ, October 2015
Completed *Advanced Comprehensive Toxicology* Course sponsored by the American College of Toxicology, University of Cincinnati, August 2015
Safety Evaluation of CNS Administered Therapeutics. Society of Toxicology Continuing Education Course; San Diego, CA, March 2015
Advances in Safety Assessment of Medical Devices. Society of Toxicology Continuing Education Course; San Diego, CA, March 2015
The Robert F. Borkenstein Course on Alcohol and Highway Safety; Testing, Research and Litigation. Indiana University: Center for Studies of Law in Action; Bloomington, IN, December 2014
Current Strategies and Methods for Evaluating Drug-Induced Cardiovascular Toxicity. Society of Toxicology Continuing Education Course; Washington, DC, March 2011

The International Conference on Harmonisation Initiatives for Conducting Pharmaceutical Preclinical Safety Studies: New and Revised Guidelines and Challenges. Society of Toxicology Continuing Education Course; Salt Lake City, UT, March 2010
Principles and Applications of Toxicokinetics. Society of Toxicology Continuing Education Course; Baltimore, MD, March 2009
Practical Strategies for Evaluation of Immunosuppression in Pharmaceutical Development. Society of Toxicology Continuing Education Course; San Diego, CA, March 2006
Fundamentals of Risk Assessment and Applications of Recent Methodologies to Difficult Problems. Society of Toxicology Continuing Education Course; Salt Lake City, UT, March 2003
Evaluation of Immunomodulation in Safety Assessment. Society of Toxicology Continuing Education Course; Salt Lake City, UT, March 2003
A Practical Approach to Blood and Lymphoid Tissue (BLT) in Toxicology Assessments. Society of Toxicology Continuing Education Course; Nashville, TN March 2002
Pulmonary Immunotoxicology. Society of Toxicology Continuing Education Course; Philadelphia, PA, March 2000
In Vitro Methods for Evaluation Biokinetic Parameters for Risk Assessment. Society of Toxicology Continuing Education Course; New Orleans, LA, March 1999

TRAINING

Completed Becton Dickinson's week long FACSCalibur training seminar, San Jose, CA, 1999
Completed two day interview training course, Farmington, MI, 2013
Participated in videotaped mock interview, Farmington, MI, 2013

PROFESSIONAL MEMBERSHIPS

Member of the Society of Forensic Toxicology, 2019-present
Member of the American College of Toxicology, 2016-present
Member of the Society of Toxicology, 1999-present
Member of the National Safety Council; Alcohol, Drugs, and Impairment Division, 2020-present

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AWARDS

- Nominated in 2011 for best drug development team at Pfizer
- Received Pfizer individual performance awards in 2010 and 2011 for work on drug safety programs
- Received Pfizer individual performance awards for involvement with SOT Pfizer committee
- Awarded NIH Post-Doctoral Training Grant: Dates: 9/1/00-8/31/02
- Received travel awards from the Society of Toxicology and Wayne State University to attend the 2000 Society of Toxicology meeting
- Recipient of the graduate student immunotoxicology specialty section award, 1999 Society of Toxicology meeting
- Recipient of the graduate student metals specialty section award, 1998 Society of Toxicology meeting
- Dean's list (undergraduate): '86, '87, & '89

PUBLICATIONS

1. **Whitekus, M. J.,** R.P. Santini, A.J. Rosenspire, and M.J. McCabe, Jr., *Protection Against CD95-mediated Apoptosis by Inorganic Mercury in Jurkat T Cells*, J. Immunol. 162:7162-7170, 1999
2. **Whitekus, M. J.**, Ning Li, Min Zhang, Meiying Wang, Marcus A. Horwitz, Sally K. Nelson, Lawrence D. Horwitz, Nicholas Brechun, David Diaz-Sanchez, and Andre E. Nel, *Thiol Antioxidants inhibit the Adjuvant Effects of Aerosolized Diesel Exhaust Particles in a murine model for Ovalbumin Sensitization*, J. Immunol. 168:2560-2567, 2002
3. McCabe, M.J., **Michael J. Whitekus**, Joogyung Hyun, Kevin G. Eckles, Geniece McCollum, and Allen J. Rosenspire, *Inorganic Mercury Attenuates CD95-mediated Apoptosis By Interfering with Formation of the Death Inducing Signaling Complex*, Toxicol Appl Pharmacol.190(2):146-56, 2003
4. Finkelman, F. D., M. Yang, T. Orekhova, E. Clyne, J. Bernstein, **M. Whitekus**, D. Diaz-Sanchez and S. C. Morris. *Diesel exhaust particles suppress in vivo IFN-gamma production by inhibiting cytokine effects on NK and NKT cells*, J Immunol, 172:3808-3813, 2004
5. McCabe, Jr., M. J., Eckles, K. G., Langdon, M., Clarkson, T. W., **Whitekus, M. J**., and Rosenspire, A. J. *Attenuation of CD95-Induced Apoptosis by Inorganic Mercury: Caspase-3 Is Not a Direct Target of low levels of Hg^{2+}, Toxicol. Lett.,* 155(1): 161-70, 2005
6. Rivera, S.P., Hyun Ho Choi, Brett Chapman, **M. J. Whitekus**, Mineko Terao, Enrico Garattini, and Oliver Hankinson*, Identification of Aldehyde Oxidase 1 and Aldehyde Oxidase Homologue 1 as Dioxin-Inducible Genes.* Toxicology 207(3):401-9, 2005

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ABSTRACTS

1. **Whitekus, M. J.,** K.P. Singh, A.J. Rosenspire, and M.J. McCabe, Jr., *Inorganic Mercury Attenuates CD95-mediated Cell Death*. Mechanisms of Immunotoxicology 12th Annual Conference: Role of Apoptosis in Immunotoxicology, Morgantown, WV, 1997 (Poster Presentation)
2. **Whitekus, M. J.** and M.J. McCabe, Jr., *Inorganic Mercury Induces Tyrosine Phosphorylation and Attenuates CD95/Fas-mediated Cell Death*. The Toxicologist, Vol. 42, No. 1-S, Abstract #1760, pg 357. Society of Toxicology Annual Meeting, Seattle, WA, 1998 (Platform Presentation).
3. **Whitekus, M.J.,** I. Heimler, and M.J. McCabe, Jr., *Mercury Suppresses CD95/Fas-Mediated Apoptosis: A Search for the Mechanism*. The Toxicologist, Vol. 48, No. 1-S Abstract #721, pg 154.Society of Toxicology Annual Meeting, New Orleans, LA, 1999 (Poster Presentation)
4. **Whitekus, M.J**., B.S. Chelladurai, A.J. Rosenspire and M.J. McCabe, Jr., *Dysregulation of CD95-mediated Apoptosis by Mercury*. The Toxicologist, Vol. 54, No. 1 Abstract #542.Society of Toxicology Annual Meeting, Philadelphia, PA, 2000 (Poster Presentation)
5. Fred D. Finkelman, Tatyana Orekhova, **Michael Whitekus** and David Diaz-Sanchez, *Selective inhibition of IFN-g secretion by Diesel Exhaust Particles*. The American Academy of Allergy, Asthma, and Immunology Annual Meeting, New York City, NY, 2002 (Poster Presentation)
6. **Whitekus, M.J**., M. Zhang, N. Li, M. Horwitz, S.K. Nelson, N. Brechun, D. Diaz-Sanchez and A. Nel, *Thiol Antioxidants inhibit the Adjuvant Effects of Aerosolized Diesel Exhaust Particles in a murine model for Ovalbumin Sensitization*. The Toxicologist, Vol. 66, No. S-1 Abstract #373 page 77. Society of Toxicology Annual Meeting, Nashville, TN, 2002 (Poster Presentation)
7. **Whitekus, M.J.,** and D. Diaz-Sanchez, *Short-Term Exposure to Inhaled Diesel Exhaust Particles Enhances Asthma-Like Symptoms in the Low IgE Responder C57BL/6 Mouse*. The Toxicologist, Vol. 72, No S-1 Abstract #590 page 121. Society of Toxicology Annual Meeting, Salt Lake City, UT, 2003 (Platform Presentation)
8. **Whitekus, M.J.**,N Brechun, S K Nelson, O Hankinson, and D Diaz-Sanchez, *Short-Term Exposure To Inhaled Diesel Exhaust Particles Enhances Asthma-Like Symptoms And Increases Cyp1a1 mRNA Levels*. The Toxicologist, Vol. 48, No. 1-S, Abstract #1398. Society of Toxicology Annual Meeting, Baltimore, MD, 2004 (Poster Presentation)
9. **M J Whitekus**, S Ritz, D Diaz-Sanchez, Suloraphane, a Potent Phase 2 Inducer, Inhibits the Adjuvant Effect of Aerosolized Diesel Exhaust Particles in a Murine Model for Ovalbumin Sensitization. The Toxicologist, Vol. 84, No. S-1, Abstract #458 page 93. Society of Toxicology Annual Meeting, New Orleans, LA, 2005 (Poster Presentation)

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TEACHING EXPERIENCE

1991 to 1992 **Eastern Michigan University**, Ypsilanti, MI
Graduate Teaching Assistant

- Supervised undergraduate general chemistry, life science, and basic chemistry lab

1990 **Gabriel Richard High School**
Student Teacher for Michigan State Secondary Provisional Certification (Chemistry/Math) Grades 7-12

- Taught two high school chemistry classes and three high school math class