

BIOGRAPHICAL SKETCH

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| NAME R. Woodrow Setzer | POSITION TITLE Mathematical Statistician | | |
| eRA COMMONS USER NAME | | | |
| EDUCATION/TRAINING | | | |
| INSTITUTION AND LOCATION | DEGREE <i>(if applicable)</i> | YEAR(s) | FIELD OF STUDY |
| University of Chicago, Chicago, Illinois | B.A | 1974 | Mathematics |
| SUNY at Stony Brook, Stony Brook, New York | Ph.D. | 1983 | Ecology and Evolution |
| University of North Carolina, Chapel Hill | Post-doc | 1987 | Biostatistics |
| National Research Council Fellow, USEPA, RTP, NC | Post-doc | 1989 | Biostatistics and Risk Assessment |

A. POSITIONS and HONORS

Research and Professional Experience:

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| Mathematical Statistician, NCCT, ORD, EPA | 2005 – present |
| Mathematical Statistician, PKB, ETD, NHEERL, ORD EPA | 2002 – 2005 |
| Adjunct Associate Professor, Department of Biostatistics, School of Public Health, University of North Carolina at Chapel Hill | 2000 – 2008 |
| Mathematical Statistician, BRSS, NHEERL, ORD | 1993 – 2002 |
| Health Scientist, HERL, ORD EPA | 1989 – 1993 |
| Postdoctoral Fellow, DTD, HERL, ORD EPA | 1987 – 1989 |
| Postdoctoral Fellow, Department of Biostatistics, School of Public Health, University of North Carolina, Chapel Hill, NC | 1984 – 1987 |
| Lecturer, Department of Ecology and Evolution, State University of New York, Stony Brook, NY | 1984 |

Professional Societies and Affiliations:

Society for Risk Analysis
 Biometrics Society
 American Statistical Association

Honors and Awards:

Level I USEPA Science and Technology Achievement Award for BBDR Modeling of the Developmental Toxicity of 5-FU, 1994
 Level III USEPA Science and Technology Achievement Award for Dose-Response Relationship in Multi-stage Carcinogenesis, 1994
 Honorable Mention, USEPA Science and Technology Achievement Award for A New Mechanism for the Exogenous Mitigation of 5-Fluorouracil-Induced Toxicity, 1997
 USEPA Silver Medal for the Organophosphate Cumulative Risk Assessment, 2003
 USEPA Bronze Medal for Commendable Service for Development of Benchmark Dose Software, 2004
 USEPA Silver Medal for Scientific Workgroups for EPA's Guidelines for Carcinogen Risk Assessment and Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens, 2006
 USEPA Bronze Medal for Commendable Service for work with the Malathion RED team, 2006.
 Honorable Mention, USEPA Science and Technology Achievement Award for Defining Different Populations of Supernumerary Ribs and Assessing their Biological and Regulatory Significance, 2006
 USEPA Bronze Medal for Commendable Service for Information Technology Improvement Project Team, 2007

Level III USEPA Science and Technology Achievement Award for Facilitating the Evaluation and Utilization of Physiologically Based Pharmacokinetic (PBPK) Models in Risk Assessment, 2007
Honorable Mention, USEPA Science and Technology Achievement Award for ToxCast: A Biologically and Chemically Based System for EPA Program Offices to Prioritize Toxicity Testing of Chemicals
USEPA Bronze Medal for “Successful Completion of a Decade’s Work Involving Cutting Edge Science and Innovation on the N-Methyl Carbamate Cumulative Risk Assessment”, 2008
USEPA Bronze Medal for Efforts as Part of a Team Instrumental in Developing and Implementing the BMD Methodology for Use in IRIS Assessments, 2008.
Award for Exceptional or Outstanding ORD Technical Assistance to the Regions or Program Offices, 2008.

Selected invitations at National & International Symposia:

1. Risk Assessment Using EPA Benchmark Dose Software Version 1.2. A full day workshop presented (with J. Gift) at the annual meeting of the Society for Risk Analysis, December 5, 1999
2. Calculating and Using Benchmark Doses (BMD). Federal/State Toxicology and Risk Analysis Committee, May 21–23, 2001.
3. Populations and PK Models. NERL/NHEERL Exposure to Dose Modeling Workshop, Research Triangle Park, NC, July 10–11, 2001.
4. Basic Statistical Analysis of Developmental Toxicity Studies, *in* Experimental Design and Biostatistics, a mini-education course at the annual meeting of the Teratology Society, Scottsdale, AZ, June 25, 2002.
5. Use of NOAEL, benchmark dose, and other models for human risk assessment of hormonally active substances. SCOPE/IUPAC International Symposium on Endocrine Active Substances, Yokohama, Japan, November 17–21, 2002.
6. Cumulative Risk Analysis for Organophosphorus Pesticides. Society of Toxicology, Salt Lake City, UT, March 9–13, 2003.
7. Mediating the Meeting between Model and Data: Statistical Issues for PBPK Modeling. International Workshop on Uncertainty and Variability in Physiologically Based Pharmacokinetic (PBPK) Models, Research Triangle Park, NC. October 31 – November 2, 2006.
8. International Workshop on Uncertainty and Variability in Physiologically Based Pharmacokinetic Models. An International Workshop on the Development of Good Modelling Practice for PBPK Models. Chania, Crete, Greece. April 26 – 28, 2007.
9. Lessons Learned: Modeling Cancer Data. ILSI Europe Workshop on the Application of Margin of Exposure (MoE) Approach to Compounds in Food which are both Genotoxic and Carcinogenic, Rhodes, Greece, October 1 – 3, 2008.

Selected Expert Committees/Advisory Panels/Organizing Committees:

Member, Editorial Board, *Toxicology Methods*, 1994 – 1998
President-Elect, Research Triangle Chapter, Society for Risk Analysis, 2001 – 2002
Chair, Research Triangle Chapter, Society for Risk Analysis, 2002 – 2003
Affiliate Member of the Biostatistics and Epidemiological Methods Facility Core, University of North Carolina at Chapel Hill Center for Environmental Health and Susceptibility
ILSI HESI Dose Dependent Transitions in Mechanisms of Toxicity Committee 2002 – 2003.
Invited Participant, WHO/IPCS Author’s Workshop on Dose-Response Modeling, Geneva, Switzerland, 2004
Invited Participant, EFSA/WHO International Conference, “Risk Assessment of Compounds that are both Genotoxic and Carcinogenic” Brussels, Belgium, 16 – 18 November, 2005
ILSI-Europe Expert Group on the Application of the Margin of Exposure Approach to Genotoxic Carcinogens in Food. 2006 – 2008.
Associate Editor for Journal of Statistical Software, 2007 -- present.

Selected Assistance/Advisory Support to the Agency:

Planning Committee and epidemiology session Chair Mn/MMT Workshop held in Research Triangle Park, NC, March 12–15, 1991
Co-Chair, Organizing Committee for the First HERL Symposium: *Biological Mechanisms and Quantitative Risk Assessment*, 1992 – 1993.

IRIS RfD/C Committee, 1994–1995

Chair, Risk Assessment Forum Technical Panel, Benchmark Dose Technical Guidance Document, 1998 – 2005

Statistical Consultant/Collaborator with the National Center for Environmental Assessment for Development of EPA's Benchmark Dose Software. 1993 – present.

Co-Chair, International Workshop on Uncertainty and Variability in Physiologically Based Pharmacokinetic Models (2006 – present; workshop Oct 31 – Nov 2, 2006).

Member, NCEA Statistical Working Group (2005 – present).

Member, ORD Information Technology Improvement Project Working Group (2006).

B. SELECTED PUBLICATIONS (selected from 53 total).

1. Scheerer JB, Xi L, Knapp GW, Setzer RW, Bigbee WL, and Fuscoe JC (1999) Quantification of Illegitimate V(D)J Recombinase-Mediated Mutations in Lymphocytes of Newborns and Adults. *Mutation Research*, 431: 291-303.
2. Hurst CH, DeVito MJ, Setzer RW, and Birnbaum LS (2000) Acute Administration of 2,3,7,8-Tetrachlorodibenzo-*p*-dioxin (TCDD) in Pregnant Long Evans Rats: Association of Measured Tissue Concentrations with Developmental Effects. *Toxicological Sciences* 53: 411-420.
3. Lau C, Andersen ME, Crawford-Brown D, Kavlock RJ, Kimmel CA, Knudsen TB, Muneoka K, Rogers JM, Setzer RW, Smith G, and Tyl R (2000). Evaluation of Biologically Based Dose-Response Modeling for Developmental Toxicity: A Workshop Report. *Regulatory Toxicology and Pharmacology*, 31: 190–199.
4. DeWoskin RS, Barone S Jr., Clewell HJ, Setzer RW (2001) Improving the development and use of biologically based dose response models (BBDR) in risk assessment. *Human and Ecological Risk Assessment*, 6: 1091 – 1120.
5. Lau C, Mole ML Copeland MF, Rogers JM, Kavlock RJ, Shuey DL, Cameron AM, Ellis DH, Logsdon TR, Merriman J, and Setzer RW (2001) Toward a biologically based dose-response model for developmental toxicity of 5-fluorouracil in the rat: Acquisition of experimental data. *Toxicological Sciences*, 59: 37–48.
6. Setzer RW, Lau C, Mole ML, Copeland FM, Rogers JM, and Kavlock RJ (2001). Toward a biologically-based dose-response model for developmental toxicity of 5-fluorouracil in the rat: a mathematical construct. *Toxicological Sciences*, 59: 49–58.
7. Shaughnessy DT, Setzer RW, and DeMarini DM (2001). Effect of the antimutagens vanillin and cinnamaldehyde on the spontaneous mutation spectra of Salmonella TA104. *Mutation Research*, 480–481: 55–69.
8. Wubah JA, Setzer RW, and Knudsen TB (2001). Exposure-disease continuum for 2-chloro-2'-deoxyadenosine (2CdA), a prototype ocular teratogen. 1. Dose-response analysis. *Teratology*, 64: 154–169.
9. Lau C, Narotsky MG, Lui D, Best D, Setzer RW, Mann PG, Wubah JA, and Knudsen, TB (2002). Exposure-disease continuum for 2-chloro-2'-deoxyadenosine (2-CdA), a prototypet teratogen: Induction of lumbar hernia in the rat and species comparisons for the teratogenic responses. *Teratology* 66: 6–18.
10. Knapp GW, Setzer RW, Fuscoe JC (2003). Quantitation of aberrant interlocus T-cell receptor rearrangements in mouse thymocytes and the effect of the herbicide 2,4-dichlorophenoxyacetic acid. *Environmental Molecular Mutagenesis*, 42: 37–43.
11. Rogers JM, Setzer RW, Branch S, Chernoff N (2004). Chemically induced supernumerary lumbar ribs in CD-1 mice: size distribution and dose response. *Birth Defects Research*, 71: 17–25.
12. Smialowicz RJ, Burgin DE, Williams WC, Diliberto JJ, Setzer RW, Birnbaum LS (2004). Xyp1A2 is not required for 2,3,7,8-tetrachlorodibenzo-*p*-dioxin-induced immunosuppression. *Toxicology*, 197, 15–22.
13. Slikker W, Andersen ME, Bogdanffy MS, Bus JS, Cohen SD, Conolly RB, David RM, Doerrer NG, Dorman DC, Gaylor DW, Hattis D, Rogers JM, Setzer RW, Swenberg JA, Wallace K (2004). Dose-dependent transitions in mechanisms of toxicity. *Toxicology and Applied Pharmacology*, 201: 203 -- 225.
14. Slikker W, Andersen ME, Bogdanffy MS, Bus JS, Cohen SD, Conolly RB, David RM, Doerrer NG, Dorman DC, Gaylor DW, Hattis D, Rogers JM, Setzer RW, Swenberg JA, Wallace K (2004). Dose-dependent transitions in mechanisms of toxicity: case studies. *Toxicology and Applied Pharmacology*, 201: 226 – 294.
15. Clark LH, Setzer RW, Barton HA (2004) Framework for evaluation of physiologically-based pharmacokinetic models for use in safety or risk assessment. *Risk Analysis* 24: 1697 – 1717.

16. Barton HA, Cogliano VJ, Flowers L, Valcovic L, Setzer RW, Woodruff TJ (2005). Assessing Susceptibility from Early-Life Exposure to Carcinogens. *Environmental Health Perspectives*, 113: 1125 – 1133.
17. Dix DJ, Houck KA, Martin MT, Richard AM, Setzer RW, Kavlock RJ. (2007). The ToxCast Program for Prioritizing Toxicity Testing of Environmental Chemicals. *Toxicological Sciences* 95: 5 – 12.
18. Barton HA, Chiu WA, Setzer RW, Andersen ME, Bailer AJ, Bois FY, DeWoskin RS, Hays S, Johanson G, Jones N, Loizou G, MacPhail RC, Portier CJ, Spendiff M, Tan Y-M (2007). Characterizing Uncertainty and Variability in Physiologically-based Pharmacokinetic (PBPK) Models: State of the Science and Needs for Research and Implementation. *Toxicological Sciences*, 99: 395 – 402.
19. Kavlock RJ, Ankley G, Blancato J, Breen M, Conolly R, Dix D, Houck K, Hubal E, Judson R, Rabinowitz J, Richard A, Setzer RW, Shah I, Villeneuve D, Weber E. (2008). Computational toxicology – a state of the science mini review. *Toxicological Sciences* 103: 14 – 27.
20. Judson R, Elloumi F, Setzer RW, Li Z, Shah I. (2008) A comparison of machine learning algorithms for chemical toxicity classification using a simulated multi-scale data model. *BMC Bioinformatics*. 2008 May 19;9:241.
21. Wambaugh JF, Barton HA, Setzer RW. 2009. Comparing models for PFOA pharmacokinetics using Bayesian analysis. *Journal of Pharmacokinetics and Pharmacodynamics*: *in press*.