

CURRICULUM VITAE

MYRA LEE WEINER, Ph.D., D.A.B.T., Fellow A.T.S.

President, TOXpertise, LLC

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EDUCATION

B.A. *cum laude* from Stern College for Women of Yeshiva University (1966)

Biology major, Chemistry minor, Regents Scholar

United States Public Health Service Predoctoral Fellow, 1966-71, Downstate Medical Center

Ph.D. in Pharmacology from the State University of New York, Downstate Medical Center (1971)

Postdoctoral Associate, University of Mississippi School of Pharmacy and Research Institute of Pharmaceutical Sciences (1971-72)

PROFESSIONAL MEMBERSHIPS / ACTIVITIES

Fellow, Academy of Toxicological Sciences, 2010-present

Diplomate of the American Board of Toxicology, 1987; re-certified in 1993, 1998, 2003, 2008, 2013

Society of Toxicology, full member since 1985

American College of Toxicology, full member 2012

Mid-Atlantic Society of Toxicology Program Committee Member (1984-87)

Member of the 1994 Teratology Delegation to the People's Republic of China, People to People International, Citizen Ambassador Program.

Company Representative to Health and Environmental Science Institute; member of the Emerging Issues Committee and Steering Committee (1997-99)

Invited Keynote Speaker at St. John's University ToxExpo Day, April 30, 2008

ToxScholar Guest Lecturer Program, Society of Toxicology, 2008

Member, Roundtable of Toxicology Consultants, 2009-present

AWARDS

1990 Corporation Health, Safety and Environmental Affairs Award for Outstanding Achievement and Exceptional Individual Effort

1990 Special Bonus Award for Outstanding Performance

1994 Process Additives Division Incentive Award for Major Contributions to the Business

2000 Nova Award for Successfully Defending a major herbicide in Europe

2005 Active Oxidants Division Special Focus Award for Persulfate HPVC Support

2011 International Pharmaceutical Excipients Council Foundation's Marshall Steinberg Memorial Award, presented at the American College of Toxicology Meeting, Nov. 2011.

EXPERIENCE SUMMARY

2008 – present: TOXpertise LLC

President and owner for consultancy practice includes the following:

- Assessment of food ingredients for self-determined GRAS positions; safety evaluations of new and existing food ingredients and recommendations for testing strategies for FDA and JECFA
- Preparation of drug/excipient master files, safety evaluation of pharmaceutical excipients and design of appropriate testing programs;
- Resolve technical questions with regulatory agencies, prepare risk assessments, toxicology study waiver requests, complete and review dossiers and summaries.
- Review toxicology data for a variety of chemicals and food additives; develop strategies for product defense and toxicology testing; publish articles in peer-reviewed journals promoting the safety of various products.

1978 – 2008: FMC Corporation

Oct. 2000 - 2008	Research Fellow, Toxicology
Oct. 1999 - Oct. 2000	Toxicology Team Leader
July - Oct. 1999	Acting Director of Toxicology
1991 - 1999	Manager, Toxicology Programs
1989 - 1991	Senior Research Toxicologist
1980 - 1989	Toxicologist
1978 - 1979	Toxicology Consultant

1976 – 1978: Adjunct Professor, Mercer County Community College

1972 – 1973: Research Institute of Pharmaceutical Sciences, University of Mississippi, Research Coordinator

RESPONSIBILITIES

Scientific study/testing program coordinator for new products

- Designed, supervised as study monitor and interpreted *in vivo* mammalian toxicity studies, including acute, developmental / reproductive toxicity, genotoxicity, dermal sensitization, chronic toxicity / carcinogenicity and neurotoxicity studies, for registration of new products.
- Planned mechanistic studies to understand compound mode of action.
- Worked with multifunctional project teams for completion of studies for submission and registration of new products.
- Met with global regulatory authorities to seek scientific input to facilitate future submissions.
- Toxicology support for the global food ingredient business, including responses to FDA and JECFA

- Designed drinking water, dietary, dermal and inhalation studies to assess potential hazards to consumers and workers.

Training and mentoring within my organization

- Chaired the Technical Training and New Technologies Team, responsible for coordinating training and evaluating new technologies to meet the needs of the Agricultural Products Division research center in Princeton, NJ.
- Developed training programs to meet the needs of the research staff.
- Mentored new toxicologists.

External Influence

- Representative to the US EPA on key company projects, including gaining agreement on study protocols, dose level selection and waiver requests for studies.
- Member of the European CEFIC Peracetic Acid Registrations' Technical Working Group, addressing registration needs and new studies under the EU Biocides Product Directive, 2005-2008.
- Company representative to the International Life Sciences Institute HESI (Health and Environmental Sciences Institute), 1995-2000.
- Active member of the Safety Committee of the International Pharmaceutical Excipients Council; prepared poster presentations and publications on the safety guidelines developed by the committee and co-edited a book on the subject, 1992-1999.
- Company representative to the Pyrethroid Working Group (PWG) Toxicology Task Force, charged with developing a research program to understand the common mechanism(s) of pyrethroid actions for the US EPA Food Quality Protection Act and cumulative risk assessment, 2000-2007.
- Company representative to the CEFIC Hydrogen Peroxide and Persulfates Task Groups, 1989-1993.
- Member of the ECETOC Hydrogen Peroxide and Peracetic Acid Task Groups, which prepared Joint Assessment of Commodity Chemicals reports (published 1993 and 2000). These reports are widely used by customers, scientists and regulators.
- Chairperson of the Technical Task Force of the Phosphates Forum of North America in the American Chemistry Council, 1998-2005. Under my leadership the first review article on inorganic phosphates in 20 years was published.

RESEARCH PUBLICATIONS

- 1) Feinstein, M.B., Paimer, M., **Lee, M.** 1968. Effect of local anesthetics on excitation-coupling mechanisms. *Trans. N.Y. Acad. Sci. Ser. II*, 30, 1073-1129.
- 2) **Weiner, M.L.** and Lee, K.S. 1972. Active calcium ion uptake by inside-out and rightside-out vesicles of red blood cell membranes. *J. Gen. Physio.* 59, 462-475.

- 3) Borne, R.F., Peden, R.L., Waters, I.W., **Weiner, M.L.**, Walz, M. 1972. Anti-inflammatory activity of para-substituted N-benzenesulfonyl derivatives of amino acids. *J. Medicinal Chem.* 15, 1325-1326.
- 4) **Weiner, M.L.** and Weiner, P.H. 1973. A study of structure activity relationships of a series of diphenylaminopropanols by factor analysis. *J. Med. Chem.* 16, 955-661.
- 5) Borne, R.F., Peden, R.L., Waters, I.W., **Weiner, M.L.**, Jordan, R., Coates, E.A. 1974. Anti-inflammatory activity of para-substituted N-benzenesulfonyl derivatives of anthranilic acid. *J. Pharmaceutical Science* 63, 615-617.
- 6) **Weiner, M.L.** 1988. Review Article: Intestinal Transport of Some Macromolecules in Food. *Journal of Food and Chemical Toxicology* 26, 867-880.
- 7) **Weiner, M.L.**, Freeman, C., McCarty, J.D., Kotkoskie, L.A., Fletcher, M.J. 1990. Dermal Toxicity/Irritation Studies of Five Inorganic Phosphates. *J. Amer. Coll. Toxicol. B*, 49.
- 8) **Weiner, M.L.**, Freeman, C., McCarty, J.D., Kotkoskie, L.A., Fletcher, M.J. 1990. Eye Irritation Studies of Five Inorganic Phosphates. *J. Amer. Coll. Toxicol. B*, 49.
- 9) **Weiner, M.L.**, Freeman, C., McCarty, J.D., Kotkoskie, L.A., Fletcher, M.J. 1990. Modified Skin Irritation Study of 75% Phosphoric Acid. *J. Amer. Coll. Toxicol. B*, 49.
- 10) McCarty, J.D., **Weiner, M.L.**, Freeman, C., Aguinaldo, E.R., Fletcher, M.J. 1990. Primary Skin Irritation Studies of Five Food Additive Plant Gums. *J. Amer. Coll. Toxicol. B*, 49.
- 11) Freeman, C., **Weiner, M.L.**, McCarty, J.D., Aguinaldo, E.R., Fletcher, M.J. 1990. Primary Eye Irritation Studies of Five Food Additive Plant Gums. *J. Amer. Coll. Toxicol. B*, 49.
- 12) **Weiner, M.L.**, Freeman, C., McCarty, J.D., Aguinaldo, E.R., Fletcher, M.J. 1990. Eye Irritation Studies on Three Concentrations of Hydrogen Peroxide. *J. Amer. Coll., Toxicol. B*, 49.
- 13) **Weiner, M.L.**, Batt, K.J., Putman, D.L., Curren, R.D., Yang, L.L. 1990. Genotoxicity Evaluation of Lithium Hypochlorite. *Toxicology* 65, 1-22.
- 14) **Weiner, M.L.** 1991. Toxicological Properties of Carrageenan. *Agents and Actions* 32, 46-51.
- 15) **Weiner, M.L.** 1992. Proposed Guidelines for Safe Use of New Excipients. *PharmTech Conference Proceedings '92*, 252-259.
- 16) Cohen, L.S., Friedman, J., Jefferson, J., Johnson, E.M., **Weiner, M.L.** 1994. A Re-evaluation of the Risk of *in utero* Exposure to Lithium, *Journal of the American Medical Association* 271 (2), 146-150.
- 17) Kotkoskie, L.A., Butt, M.T., Selinger, E., Freeman, C., **Weiner, M.L.** 1996. Qualitative investigation of uptake of fine particle size microcrystalline cellulose following oral administration in rats. *J. Anat.* 189, 531-535.
- 18) Steinberg, M., Borzelleca, J.F., Enters, E.K., Kinoshita, F.K., Loper, A., Mitchell, D.B., Tamulinas, C.B., **Weiner, M.L.** 1996. A New Approach to the Safety

- Assessment of Pharmaceutical Excipients. *Regulatory Toxicol. and Pharmacol.* 24, 149-154.
- 19) J.-F. Régnier · C. Clare · J. de Gerlache · G. Malinverno · W. Mayr · **M. Weiner** · H. Trochimowicz. 1997. P XVII A.13 Ex vivo and in vitro unscheduled DNA synthesis (UDS) assays in rat liver with hydrogen peroxide. *Mutation Research/Fundamental and Molecular Mechanisms of Mutagenesis*.
 - 20) Auletta, C.S., **Weiner, M.L.**, Richter, W.R. 1998. A Dietary Oncogenicity Study of Tributyl Phosphate in the Rat. *Toxicology* 128, 125-134.
 - 21) **Weiner, M.L.** and Jortner, B. 1999. Review Article: Organophosphate-Induced Neurotoxicity of Triaryl Phosphates. *NeuroToxicology* 20, 653-674.
 - 22) **Weiner, M.L.**, Freeman, C., Trochimowicz, H., deGerlache, J., Jacobi, S., Malinverno, G., Mayr, W., Regnier, J.F. 2000. Thirteen Week Drinking Water Toxicity Study of Hydrogen Peroxide in Catalase-Deficient Mice. *Food and Chemical Toxicology* 38, 607-615.
 - 23) **Weiner, M.L.**, Salminen, W.F., Larson, P.R., Barter, R.A., Kranetz, J.L., Simon, G. S. 2001. Toxicological Review of Inorganic Phosphates. *Food and Chemical Toxicology* 39, 759-785.
 - 24) Soderlund, D.M., Clark, J.M., Sheets, L.P., Mullin, L.S., Piccirillo, V.J., Sargent, D., Stevens, J.T., **Weiner, M.L.** 2002. Mechanisms of pyrethroid neurotoxicity: implications for cumulative risk assessment. *Toxicology* 171, 3-59.
 - 25) Freeman, C., **Weiner, M.L.**, Kotkoskie, L.A., Borzelleca, J., M. Butt. 2003. Subchronic and Developmental Toxicity Studies in Rats with Ac-Di-Sol[®] Crosscarmellose Sodium. *International J. of Toxicol.* 22, 149-157.
 - 26) **Weiner, M.L.**, Nuber, D., Blakemore, W., Harriman, J.F., Cohen, S.M. 2007. A 90-Day Dietary Study on Kappa Carrageenan with Emphasis on the Gastrointestinal Tract. *Food and Chemical Toxicology* 45, 98-106.
 - 27) **Weiner, M.L.**, Nemeč, M., Sheets, L., Sargent, D. and Breckenridge, C. 2009. Comparative Functional Observational Battery Study of Twelve Commercial Pyrethroid Insecticides Following Acute Oral Exposure in Male Rats. *NeuroToxicology*, 30S, 1S-16S
 - 28) Breckenridge, C., Holden, L., Sturgess, N., **Weiner, M.L.**, Sheets, L., Sargent, D., Soderlund, D., Choi, J.S., Symington, S., Clark, J., Burr, S. and Ray, D. 2009. Evidence for Separate Mechanisms of Toxicity of Type I and Type II Pyrethroid Insecticides. *NeuroToxicology* 30S, 17S-31S.
 - 29) **Weiner, M.L.** 2014. Food Additive Carrageenan: Part II: A Critical Review of Carrageenan *In Vivo* Safety Studies. *Critical Reviews in Toxicology* 40 (3): 244-269.
 - 30) **Weiner M.L.**, Ferguson H.E, Thorsrud B.A., Nelson K.G., Blakemore W.R., Zeigler B., Cameron M.J., Brant. A., Cochrane L., Pellerin M. and Mahadevan B. 2015. An Infant Formula Toxicity and Toxicokinetic Feeding Study on Carrageenan in Prewaning Piglets with Special Attention to the Immune System and Gastrointestinal Tract. *Food Chem Toxicol.* 77: 120-131.
 - 31) Zeigler, B. M., Cameron, M., Nelson, K., Bailey, K, **Weiner, M.L.**, Mahadevan, B. and Thorsrud, B. 2015. The Development and Validation of Methods for

- Evaluating the Immune System in Prewearing Piglets. *Food Chem Toxicol.* 84:197-207.
- 32) **Weiner, M.L.**, 2016 Parameters and pitfalls to consider in the conduct of food additive research, Carrageenan as a case study. *Food Chem Toxicol.* 87; 31-44.
 - 33) McKim, J.M., Baas, H., Rice, G.P., Willoughby, J.A., Sr., **Weiner, M.L.**, Blakemore, W.R. 2016. Effects of carrageenan on cell permeability, cytotoxicity, and cytokine gene expression in human intestinal and hepatic cell lines. *Food Chem Toxicol.* 96; 1-10.
 - 34) **Weiner, M.L.**, McKim, J.M., Blakemore, W.R. 2017. Addendum to Weiner, M.L. (2016) Parameters and Pitfalls to Consider in the Conduct of Food Additive Research, Carrageenan as a Case Study. *Food Chem Toxicol.* 107, 208-214.
 - 35) McKim, J.M., Willoughby, J.A. Sr., Blakemore, W.R., **Weiner, M.L.** 2018. Clarifying the Confusion Between Degraded Carrageenan, Poligeenan and Carrageenan: A review of the chemistry, nomenclature, and *in vivo* toxicology by the oral route. *Critical Reviews in Food Science and Nutrition*, <https://doi.org/10.1080/10408398.2018.1481822>
 - 36) **Weiner, M.L.** and McKim, J.M. 2019. Comment on “Revisiting the carrageenan controversy: do we really understand the digestive fate and safety of carrageenan in our foods?” by S. David, C. S. Levi, L. Fahoum, Y. Ungar, E. G. Meyron-Holtz, A. Shpigelman and U. Lesmes,. *Food and Function*, 10, 1760-1762. DOI: 10.1039/c8fo01282b and <https://pubs.rsc.org/en/content/articlehtml/2019/FO/C8FO01282B>
 - 37) McKim, J.M., Willoughby, J.A., Blakemore, W.R. and **Weiner, M.L.** 2019 Review A Critical Review of “A randomized trial of the effects of the no-carrageenan diet on ulcerative colitis disease activity. (Nutr. Healthy Aging. 2017; 4(2): 181–192). *Nutr. Healthy Aging*.
 - 38) McKim, J.M., Willoughby, J.A., Blakemore, W.R. and **Weiner, M.L.** 2019. Gastrointestinal Tract Digestion and Carrageenan: How Misconceptions have influenced the Understanding of Carrageenan Safety. *J. Nutritional Biology* 5(1): 364-376.

MONOGRAPHS / BOOKS / CONFERENCE PROCEEDINGS

- 1) Lithium in Biology and Medicine: New Applications and Developments, 1991, Ed. by G. N. Schrauzer and K. Klippel, VCH Publishers, Inc., New York, N.Y., **Weiner, M.L.**, Overview of Lithium Toxicology, pages 81-100.
- 2) Joint Assessment of Commodity Chemicals Report No. 22: Hydrogen Peroxide, 1993. ECETOC, Brussels. Co-author.
- 3) MARINALG Monograph on Carrageenan, 1991. Co-author with L.A. Kotkoskie, submitted on behalf of International Food Additives Council (IFAC) and MARINALG.
- 4) Advances in Chitin and Chitosan, 1992, C.J. Brine, P.A. Sandford and J.P. Zikakis, eds., Elsevier Applied Science Publishers, Essex, U.K., **Weiner, M.L.**

- "An Overview of the Regulatory Status and of the Safety of Chitin and Chitosan as Food and Pharmaceutical Ingredients".
- 5) Lithium in Medicine and Biology, 1993, ed. by N.J. Birch, C. Padgham and M.S. Hughes, Marium Press, Lanshire, U.K., **Weiner, M.L.** "The Human Dose Response to Lithium - from trace to toxic levels", pages 15-25.
 - 6) Excipient Toxicity and Safety, 1999, editors, **M.L. Weiner** and L.A. Kotkoskie, Marcel Dekker, Inc. Co-author with Joseph Borzelleca of Chapter 5, Development of Safety Evaluation Guidelines.
 - 7) WorldPharm99 Proceedings, 1999, **M.L. Weiner**, Principles of Safety Assessment of New Pharmaceutical Excipients. Invited speaker.
 - 8) Joint Assessment of Commodity Chemicals Report No. 40: Peracetic Acid, 2001. ECETOC, Brussels. Co-author.
 - 9) Weiner, M.L. 2018 Chapter in Her STEM Career: Adventures of 51 Remarkable Women, Ed. Diane Propsner, Book 1, p. 187-190.
 - 10) **Weiner, M.L.** 2019 Uprooting the Poison Tree, Published by Eliezer Tristan Publishing, LLC.

INTERNATIONAL MEETINGS

- 1) Fifth International Congress of Toxicology (IUTOX), 1989, Brighton, England, Authored and presented two papers: "Lack of Genotoxicity of Ac-Di-Sol® " and "Acute Toxicity of Carrageenan."
- 2) Twelfth European Workshop of Inflammation, May 1990, Halle, East Germany, Invited Speaker on "Toxicological Properties of Carrageenan."
- 3) Present Status and Perspectives on Lithium in Biology and Medicine, May 1990, Nonweiler, West Germany, Invited speaker on "Overview of Lithium Toxicology."
- 4) Fifth International Conference on Chitin and Chitosan, Oct., 1991, Princeton, New Jersey, Invited Speaker on "Overview of the Regulatory Status and of the Safety of Chitin and Chitosan as Food and Pharmaceutical Ingredients."
- 5) Sixth International Congress of Toxicology (IUTOX), June 1992, Rome, Italy, Co-authored and submitted two papers: "Safety Evaluation of the FMC's Paper Deacidification Process" and "Acute Toxicity Evaluation of Ac-Di-Sol® and Avicel® PH, Avicel® RC and CL: Pharmaceutical Excipients."
- 6) Third British Lithium Congress, Sept. 1992, Wolverhampton, England, Invited Speaker on "The Human Dose Response to Lithium - from trace to toxic levels."
- 7) First International Congress on Teratology in China, Chengdu, China, Invited Speaker on "A Review of the Risks of Birth Defects Associated with Drug Exposure to Lithium," May, 1994.
- 8) Malta Lithium Symposium, Invited Speaker on "Environmental Regulation of Lithium Carbonate in the United States". November, 1995.
- 9) Eighth International Congress of Toxicology, July, 1998, Paris, France. Presenter for CEFIC Hydrogen Peroxide Toxicity Work Group for "A 13-Week Drinking Water Study with 6-Week Recovery Period in Catalase-Deficient Mice with Hydrogen Peroxide."

- 10) Ninth International Congress of Toxicology, July, 2001, Brisbane, Australia. Presenter for American Chemistry Council of the Americas for “Rationale for a Single Category Approach for Inorganic Phosphates” and for FMC Corporation for “Carfentrazone-ethyl: Evidence for a protox mechanism of toxicity in subchronic and chronic toxicity studies in rats, mice and dogs.”
- 11) Society of Toxicology, Co-chaired a workshop on “Challenges of the Developmental Neurotoxicity Study” with US EPA scientist, Ms. Susan Makris, at the Society of Toxicology meeting, March 2003.
- 12) International Pharmaceutical Conference & Expo, March 2018, Philadelphia, PA USA. Keynote Address, “Parameters and pitfalls to consider for the conduct of pharmaceutical excipient and food additive research, carrageenan as a case study.”