Testimony of Michelle L. Twaroski, Ph.D.
In Opposition to HB 6498,

An Act Concerning Cadmium Levels in Children's Jewelry

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March 5, 2013

Oral Testimony

Good morning and thank you for this opportunity to testify in opposition of An Act Concerning Cadmium in Children's Jewelry, H.B. 6498. Specifically the Act should be amended to align with newer information from the Consumer Product Safety Commission's (CPSC) evaluation of cadmium and the American Society for Testing and Materials (ASTM) standard regarding children's jewelry. I am Michelle Twaroski, Ph.D., a toxicologist employed by the law firm Keller and Heckman, LLP, located in Washington, DC. I have been working in the field of toxicology for over 20 years as either a research scientist or a risk assessor. Prior to joining the staff, I spent over a decade as a toxicologist at the Food and Drug Administration ("FDA"), the majority of the time supervising safety reviews. My last position within the government was as a branch chief in the Environmental Protection Agency ("EPA"). Moreover, I have a decade of experience supervising safety assessments of industrial chemicals either for direct consumption as a result of their use in food packaging or as new chemicals to be used in commerce. In working on submissions to these agencies or through special assessments, I have worked on a number of issues regarding the risk analysis of infant and child exposures to industrial chemicals.

The first issue I wish to emphasize in my testimony is that risk assessments of chemicals involve a standard process in determining whether a safe level of exposure exists.[1] These include identifying an adverse effect, the relationship between a dose of the chemical and the adverse response, and estimating the current exposure to the chemical. It is important to realize that a low exposure to a compound may be without an effect; however, a much larger exposure to that same compound may overwhelm biological systems leading to toxicity - hence the phrase "the dose makes the poison." Therefore, an accurate estimate of the exposure must be considered. In this regard, it is important to acknowledge that the presence of a material in a formed article does not necessarily mean that exposure will occur at the level of content, since it is rare that all of the substance will be released. Lastly, the risk characterization must be conducted to determine what a safe level of exposure is for the population as a whole based on

[1] Risk Assessment in the Federal Government: Managing the Process. Washington, DC: The National Academies Press, 1983; Faustamn, E. M and Omenn, G. S. Risk Assessment. Casarett & Doull's Toxicology. The Basics Science of Poisons. Klaassen, C. D. ed. 6th Edition. McGraw Hill Professional, 2001

information on the mechanism and uncertainty in the data set. **The Consumer Product Safety Commission (CPSC) employed these standard steps of the risk assessment process in its review of Children's Cadmium – Containing Metal Jewelry.**[2]

The main focus of cadmium risk assessments are dietary and occupational exposure scenarios. Adverse effects can occur either though an acute exposure or by the accumulation of cadmium in the body over time; these include reduced body weight and food consumption, gastric damage, liver damage, bone toxicity, kidney damage and death. **The large dataset on these endpoints and others, as well as the mechanism of toxicity and the persistence of the compound, were considered in CPSC's recent comprehensive assessment of cadmium, and informed its conclusion regarding an acceptable toxicological end point for modeling the safe level of cadmium in children's jewelry.**

In CPSC's assessment of cadmium safety for children's jewelry, the staff determined an acute and chronic safe level. [3] The chronic safe level was based on human data and early markers of kidney damage. Results from the human study were adjusted based on considerations of human variability in the population to conclude a safe level of 0.1 µg/kg bw/day or 1.8 µg/day for a child. For acute exposures, such as accidental ingestion, animal data were used based on two adjustment factors, one for sensitive people and one for differences between rats and humans. The acute safe level was 11 µg/kg bw or 200 µg. **As such, the CPSC's safe levels consider susceptible individuals in the population according to traditional risk assessment techniques.**

In addition to peer review, one can also examine other existing reference doses as a comparison to the conclusions of the CPSC.[4] Again, most of these values are an assessment from dietary sources, since these sources will provide the bulk of lifetime exposures.

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[2] Children's Cadmium-Containing Metal Jewelry; United States Consumer Product Safety Commission October 14, 2010. Accessible at http://www.cpsc.gov/PageFiles/96163/cadmiumjewelry.pdf

[3] Children's Cadmium-Containing Metal Jewelry; United States Consumer Product Safety Commission October 14, 2010 And Toxicity Review of Cadmium October 14, 2012. Accessible at http://www.cpsc.gov/PageFiles/96163/cadmiumjewelry.pdf

[4] Reviewed in World Health Organization review Draft Series 46 available online at http://www.inchem.org/documents/jecfa/jecmono/v46je11.htm ; 52 (addendum) http://www.inchem.org/documents/jecfa/jecmono/v52je22.htm and Previous reviews by Joint FAO/WHO Expert Committee on Food Additives http://www.inchem.org/documents/jecfa/jeceval/jec_297.htm ; Agency for Toxic Substances & Disease Registry Toxicological Profile for Cadmium Available online at http://www.atsdr.cdc.gov/substances/toxsubstance.asp?toxid=15 ; European Food Safety Authority. Cadmium dietary exposure in the European population. EFSA Journal 2012;10(1):2551. [37 pp.]. doi:10.2903/j.efsa.2012.2551. Available online: www.efsa.europa.eu/efsajournal ; US Environmental Protection Agency Available online: http://www.epa.gov/iris/subst/0141.htm ; Health Canada Draft Proposal for Cadmium Guidelines in Children's Jewellery Available online http://www.hc-sc.gc.ca/cps-spc/legislation/consultation/_2011cadmium/draft-ebauche-eng.php#a11

International safe chronic values reviewing the same or similar data concluded safe levels of 1.5 µg/kg bw/day to 0.1 µg/kg bw/day. The Canadian government has also determined an acute value of 0.0732 mg/kg bw or 0.9516 mg for a 13 kg child. **Therefore the CPSC's safe levels are equivalent to or more conservative than other highly regarded assessments of cadmium.**

Turning to exposure, CPSC has determined a method for conservatively estimating acute and chronic exposure to children's jewelry based on scientific data on biological simulants and children's behavior. Furthermore, data generated by CPSC and industry indicate that there is no strict relationship between cadmium content in metal and cadmium extraction; however, higher content does result in higher cadmium levels in extraction media. Data also demonstrate that there is a content level suitable to use as a starting point for requiring testing based on a lack or minimal migration and the ASTM F2923-11 standard is based on this content level as a starting point as to when migration testing should be conducted to ensure safety. That level is 300 ppm (0.03%) for covered jewelry. Using the level of 300 ppm and extremely conservative assumptions, the exposure is predicted to be well below the acute limit set by CPSC and others. Using this standard, metal jewelry over the 300 ppm cadmium content will be held to a migration limit of less than or equal to 200 µg cadmium in acidic solutions and plastic parts would be held to a limit of 75 ppm. For larger jewelry above the 300 ppm content level, a migration limit of 18 µg cadmium/day in saline would need to be met for protection against chronic exposure. The chronic assumptions are extremely conservative as they consider daily mouthing of the same piece of jewelry with 0.03% cadmium repeatedly over a chronic period.

In conclusion, the CPSC's method of analysis for extraction is based on scientific principles of physiological conditions and the assumptions used in the developing the ASTM standard are conservative based on data on actual jewelry samples examined using these protocols. The difference between the chemical content of a formed article and the actual exposure to the chemical via migration is not unique to jewelry. This approach is the basis of exposure estimates of many other scientific safety assessments (for example, food contact materials). Using exposure limits based on actual migration information as opposed to content add to the scientific robustness of the assessment.

MICHELLE L. TWAROSKI, PH.D.

PROFESSIONAL EXPERIENCE

3/12 – present Toxicologist, Keller and Heckman, LLP. , 1001 G Street NW, Suite 500 W, Washington, DC. Daily activities include risk assessments for human and environmental exposures to chemicals from their use in food or release in the environment. Includes support for FDA, EPA and REACH submissions as well as advisory opinions on GMP and contaminant issues.

10/11 – 3/12 Supervisory Toxicologist (Branch Chief), US Environmental Protection Agency (EPA), Office of Pollution Prevention and Toxics, Risk Assessment Division – Chief, New Chemicals Screening and Assessment Branch, Washington, DC (http://www.epa.gov/opptintr/newchems/index.htm)
Daily activities included supervising staff in performing risk assessments for human health and ecological endpoints for exposures to new chemicals under the authority of the Toxic Substances Control Act (TSCA). Additionally supervised the assessment of new biotechnology products (TERA, MCAN) and consulted on existing chemical assessments.

12/02 -10/11 Toxicology Group Supervisor, US Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN), Office of Food Additive Safety, Division of Food Contact Notifications, College Park, MD
Supervised staff in performing safety reviews for human health endpoints of several hundred food contact substances evaluated under the authority of the Federal Food, Drug and Cosmetic Act. Served as the lead toxicologist/technical reviewer for FDA's review of Bisphenol A (BPA) for use in food contact applications; contributed to numerous committees, including those developing guidance/policy on nanotechnology and genetic toxicology of polymeric substances; CFSAN's Cancer Assessment Committee, OMB Peer Review Bulletin committee, CFSAN's reviewer representative to the FDA Scientific Computing Computational Science Business Review Board, CFSAN's Bioinformatics Review Board, FDA's representative to IFT/ILSI nanotech in foods committee, FDA Risk Assessment Discussion Group, FDA Toxicology Study Selection and Review Committee, Structure Activity Relationship (SAR) analysis, and Infant Exposure Working group; workgroup lead in FDA Food Safety Modernization Act (FSMA) – Import Certification.

09/00-12/02 Toxicologist, US Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Food Additive Safety, Division of Food Contact Substance Notification Review, College Park, MD
Reviewed toxicology data and performed safety assessments on indirect food additives prior to marketing in the US as part of the food contact notification (FCN) program. Developed new approaches to the use of SAR modeling for carcinogenic risk assessments in regulatory decision making, contributed to the Center's Cancer Assessment Committee (CAC) and risk assessment teams, and served as a liaison to an extramural contract for toxicology support. During this time also completed a sabbatical/detail in the US Environmental Protection Agency's Office of Pollution Prevention and Toxics, New Chemicals Program regarding the use of SAR in regulatory decisions.

07/00-08/00 Postdoctoral Scholar, Graduate Center for Nutritional Sciences, University of Kentucky, Lexington, KY. P.I.: Howard P. Glauert, Ph.D.

04/93-08/95 Principal Laboratory Technician, Department of Biochemistry, University of Kentucky, Lexington, KY.
Conducted research regarding the molecular mechanisms of DNA binding and the transcriptional regulation of genes by the peroxisome proliferator activated receptor (PPAR) and its heterodimer partner, retinoid X receptor (RXR). Efforts resulted in numerous publications, book chapters, and scientific posters at international meetings.

02/92-04/93 Senior Laboratory Technician, Center for Pharmaceutical Science and Technology, University of Kentucky, Lexington, KY.
Experience primarily involving quality assurance in a contract GMP/GLP pilot plant producing pharmaceuticals for clinical trials.

EDUCATION

1995-2000 Ph.D. Toxicology
University of Kentucky, Lexington, KY
Dissertation Title: Effects of peroxisome proliferators on antioxidant enzymes, vitamins, and redox-sensitive transcription factors in rats and hamsters. Dissertation research resulted directly in three first author publications, several scientific posters and one invited review. Several additional collaborations, through developmental rotational assignments or technical advising, resulted in numerous publications and scientific posters.

1988-1991 B.A., Biology
University of Louisville, Louisville, KY

1987-1988 Morehead State University
Morehead, KY

AWARDS AND HONORS

2011 CFSAN - FSMA (Chair – Import Workgroup)
2011 CFSAN - BPA On-going review (CFSAN Chair, FDA Co-chair)
2011 Quality Step Increase for Exceptional Performance rating
2010 CFSAN - LMWO internal guidance
2010 CFSAN - Infant safety assessment group
2010 FDA Group Recognition Award - For extraordinary efforts and teamwork in developing reviews of the available toxicological, biomonitoring, and exposure information on a tight timeline while maintaining the highest level of scientific excellence.
2010 CFSAN Legacy Award - For successfully lunching the Leaders Developing Leaders Program which continues to improve and achieve intended goals.
2009 Quality Step Increase for Exceptional Performance rating
2009 CFSAN award for Excellence in Review Science for sustained leadership and scientific excellence in the toxicological review of food additives.
2009 Team Spirit Award – Exceptional performance in conducting DFCN's complex safety review of perfluoro grease proofing agents used in the manufacture of food contact paper products and non-stick coatings for cookware.
2009 Exceptional Achievement Award – For outstanding effort in developing a Peer-review Promotion Process for Regulatory Review Scientists in CFSAN that have mastered the scientific principles of the review discipline.
2008 Performance Incentive Award – Exceptional Performance Rating
2008 CFSAN Honor Award - Outstanding Service Award: For outstanding, sustained and dedicated service as a technical and managerial leader in FDA's Food Contact Notification Program
2007 Team Award - Bisphenol A Task Force – Role: Team Lead

2007	Team Award - Grease Proofing Review Team Group Recognition Award
2007	FDA Honor Award - Outstanding Service Award (Group Award): For exceptional efforts in working with the regulated industry to resolve critical and extremely complex post-market safety issues concerning perfluorochemicals
2007	CFSAN Exceptional Achievement Award (Group Honor Award): For outstanding contributions in developing guidance to implement the petition and notification processes of the Food Allergen Labeling and Consumer Protection Act.
2006	Team Award – For outstanding coordinated effort in reviewing the toxicity and regulatory data on perluoro grease proofing agents.
2006	Team Award – For developing core competencies for DFCN in consultation with Staff College and present the document, on behalf of the group, to the office management and division staff.
2006	CFSAN Honor Award, CFSAN Team Spirit Award, Core Competencies Development Team Office of Food Additive Safety - For developing an approach to identify core competencies for work in the food contact notification program to serve as a model for other similar programs
2006	FDA Scientific Achievement Award, Outstanding Intercenter Scientific Collaboration: *CDER-CFSAN Collaborative Toxicology Database and Modeling Group*
2005	Quality Step Increase (QSI)
2005	CFSAN Award of Excellence – For exceptional leadership in the developing a new risk management tool in the food additives safety review program.
2004	Team Award – For outstanding and timely work to formulate FDA's position on perfluorooctanoic acid in food.
2002	Teamwork/Collegiality Award – Exceptional management of contract reviews of toxicity studies submitted for Food Contact Notifications
2002	Group Recognition Award – Structure Activity Relationship Group
1999-2000	Dissertation Year Fellowship Recipient, Commonwealth Research Award
1998-1999	Recipient: NIH Training Grant in Toxicology
1997-1998	Recipient: NIH Training Grant in Reproductive Science
1996-1997	Recipient: NIH Training Grant in Toxicology

PROFESSIONAL ORGANIZATIONS

2000-	Society of Toxicology
2002-2003	Society of Risk Assessment

COMMITTEES/EXTRAMURAL ACTIVIES

- Environmental Defense Fund: "Chemical Testing in the 21st Century: Opportunities and Challenges." – invited expert participant, January 2013, Washington, DC.
- EFSA Scientific Colloquium XVII, On Low Dose Response in Toxicology and Risk Assessment, Parma, Italy, 14 -15 June 2012 –Participant
- Joint FAO/WHO Expert meeting to review toxicological and health aspects of Bisphenol A, Ottawa, Canada, 1-5 November 2010 – Invited expert and organizing committee member. Sections authored: Short Term Toxicity, Cardiovascular Disease, Immunotoxicology.
- Enhancing FDA's Evaluation of Science to Ensure Chemicals Added to Human Food are Safe at the Pew Conference Center in Washington, D.C. Sponsors: Nature, IFT, the Pew Health Group, 5-6 April 2011 FDA invited expert.
- Institute of Life Sciences (ILSI) North America: Committee on Food and Chemical Safety – Government Liaison, 2011
- Interagency Risk Assessment Consortium: Susceptible Populations Workshop, 01/20-21/2010
- FDA/ IFT/ILSI nanotech in foods committee,
- Guidance for Industry: Preparation and Submission of a Notification to Exempt a Food Ingredient from the Allergen Labeling Requirements of the Food Allergen and Consumer Protection Act of 2004
- Food Forum 2005 – organization team

- Peer Reviewer – *Toxicological Sciences* (2005 -); *PPAR Research* (2006)

MENTOR PROGRAMS

Leaders Developing Leaders Organizational Program (Mentor – 2 employees – 2007/08
Joint Institute for Food Safety and Applied Nutrition (Mentor – Spring 05 – Spring 2007)
Hispanic Association of Colleges and Universities (Mentor - Spring 05)
Workforce Recruitment Program (Mentor – Summer 04)
Hispanic Association of Colleges and Universities (Mentor - Spring 04)

GRANTS

Office of Women's Health: Quantum mechanical and NMR spectral approaches for the rapid prediction of estrogen activity of FDA regulated chemicals. Co-PI; $77,000
Further development and refinement of the FDA's Endocrine Disruptor Knowledge Base for assessing endocrine disrupting potential of drugs and food additives: FDA-NCTR Research Protocol: E0741501 - Outside Collaborator

PRESENTATIONS

1. U.S. safety assessment of food contact substances. Division of Chemical Toxicology, Human Exposure and Responses to Toxins from the Air and Water, Human Exposure & Responses to Toxins: Endocrine Active Chemicals in the Environment, 242nd ACS National Meeting, August 31st, 2011, Denver, CO.
2. Regulation of BPA in the United States. International Association for Food Protection 2011, August 2, 2011, Milwaukee, WI
3. U.S. Regulation of Food Contact Materials & FDA's International Information Exchange Initiatives. SPI Food, Drug, and Cosmetic Packaging Materials Committee 10th Biennial International Symposium on Worldwide Regulation of Food Packaging, June 7th, 2011
4. Regulatory Process to Ensure the Safety of Food Packaging Materials. International Association for Food Protection 2010, August 3, 2010, Anaheim, CA
5. Update on FDA approaches to evaluating toxicity data - current thinking on new toxicological endpoints, including estrogenicity. SPI Food, Drug, and Cosmetic Packaging Materials Committee (FDCPMC), December 3, 2009
6. Update – US FDA Food Contact Notifications, Food Drug and Cosmetic Packaging Materials Committee, 9th Biennial International Symposium on Worldwide Regulation of Food Packaging, June 11th, 2009
7. Draft Assessment of Bisphenol A for Use in Food Contact Applications, Public Meeting, September 16, 2008, Rockville, MD.
8. *Food Contact Notifications FY2008 Update.* Keller and Heckman Schedules Annual Food Packaging Law Seminar, Washington, October 2008
9. *An update on the Food Contact Notifications Program.* Keller and Heckman Schedules Annual Food Packaging Law Seminar, Washington, October 2007
10. *Ensuring the Safety of Food Contact Substances: The US FDA Approach*. Plastics and Paper in Contact with Foodstuffs, Washington, DC, April 18, 2007
11. *Ensuring the Safety of Food Contact Substances: The US FDA Approach*. Plastics and Paper in Contact with Foodstuffs, Washington, DC, April 19, 2006
12. *Real-time databasing*. Leadscope In Silico Toxicology Meeting. College Park, Maryland. October 5, 2005.
13. *Division of Food Contact Notifications, US FDA, update.* 21st International Plastic and Polymers in Contact with Foodstuffs, Edinburgh, UK, December 14, 2004.

14. *Safety Assessment Procedures at the Office of Food Additive Safety - Application of Risk Assessment: FDA Approach,* The Food, Drug, and Cosmetic Packaging Materials Committee, The Society of the Plastics Industry, Baltimore, MD, USA, June 2004.
15. *An Update on the Food Contact Notification Program,* 4th Annual Food Packaging Law Seminar, The conference on updates and trends in FDA food packaging regulations. Keller and Heckman, LLP. Washington, DC, USA, October 29, 2003
16. *Integrating SAR in Safety Assessments,* American Plastic's Council, Washington, DC, USA, November 2001.
17. *Carcinogenic Risk Assessment,* Premarket Notification for Food Contact Substances; Public Meeting., Bethesda, MD, USA, October 2002 (Federal Register Notice 09/18/2002, page 58809-58810).

PUBLISHED MANUSCRIPTS

1. Nelson, C.P., Patton, G.W., Arvidson, K., Lee, H., and **Twaroski, M.L**. Assessing the Toxicity of Polymeric Food-Contact Substances. *Food and Chemical Toxicology*.2011 (49) 1877-1897
2. J. Mayer, M.A. Cheeseman, **M.L. Twaroski.** Structure Activity Relationship Analysis Tools: Validation and Applicability in Predicting Carcinogens. *Regulatory Toxicology and Pharmacolog*y 2008 (50) 50-58.
3. Bailey, A.B., Chanderbhan, R., Collazo-Braier, N., Cheeseman, M., and **Twaroski. M.L.** The Use of Structure-Activity Relationship (SAR) Analysis in the Food Contact Notification (FCN) Program. *Regulatory Toxicology and Pharmacology*. 2005 July;42(2):149-252.
4. Begley, T. H., White, K., Honigfort, P., **Twaroski, M.L.**, Neches, R., and Walker, R.A. Perfluorochemicals: Potential sources of and migration from food packaging. *Journal of Food Additives and Contaminants.* 2005 Oct. 22(10):1023-1031.
5. **O'Brien, M.L.**, Cunningham, M.L., Spear, B.T. and Glauert, H.P. Peroxisome proliferators do not activate the transcription factors AP-1, early growth response-1 (Egr-1), or heat shock factors 1 and 2 (HSF1/2) in rats or hamsters *Toxicol Sci.* 2002 Sep;69(1):139-48.
6. **O'Brien, M.L.**, Twaroski, T.P., Cunningham, M.L., Glauert, H.P., and Spear, B.T. Effects of peroxisome proliferators on antioxidant enzymes and antioxidant vitamins in rats and hamsters*. Toxicol Sci.* 2001 Apr;60(2):271-8.
7. **O'Brien, M.L.**, Cunningham, M.L., Spear, B.T., and Glauert, H.P. Effects of peroxisome proliferators on glutathione and glutathione-related enzymes in rats and hamsters. *Toxicol Appl Pharmacol.* 2001 Feb 15;171(1):27-37.
8. Twaroski, T.P., **O'Brien, M.L.**, Larmonier, N., Glauert, H.P., and Robertson, L.W. Polychlorinated biphenyl-induced effects on metabolic enzymes, AP-1 binding, vitamin E, and oxidative stress in the rat liver. *Toxicol Appl Pharmacol.* 2001 Mar 1;171(2):85-93.
9. Twaroski, T.P., **O'Brien, M.L.,** and Robertson, L.W. Effects of selected polychlorinated biphenyl (PCB) congeners on hepatic glutathione, glutathione-related enzymes, and selenium status: implications for oxidative stress. *Biochem Pharmacol*. 2001 Aug 1;62(3):273-81.
10. **O'Brien, M. L.**, Park, K. S., In, Y. H. and Park-Sarge, O-K. 1999 Characterization of estrogen receptor-β (ERβ) messenger ribonucleic acid and protein expression in rat granulosa cells. *Endocrinology* 140:4530-4541.
11. Shanmugam, M. Krett, N. L., Maizels, E. T., Cutler, R. E., Peters, C. A., Smith, L. M., **O'Brien, M. L**., Park-Sarge, O-K., Rosen, S. T., and Hunzicker-Dunn, M. 1999 Regulation of protein kinase Cδ by estrogen in the MCF-7 human breast cancer cell line. *Molecular and Cellular Endo.* 148:109-118.
12. Intrasuksri, U., Rangwala, S. M., **O'Brien, M.,** Noonan, D., and Feller, D.R. 1998 Mechanisms of peroxisome proliferation by perfluorooctanoic acid and endogenous fatty acids. *General Pharmacology* 31:187-197.
13. Noonan, D. J. and **O'Brien, M. L.**. 1997 A hypothetical mechanism for fat-induced rodent hepatocarcinogenesis. *Adv Exp Med Biol* 422: 127-35.
14. Ganguly, T. C., **O'Brien, M. L.**, Karpen, S. J., Hyde, J. F., Suchy, F. J. and Vore, M. 1997 Regulation of the rat liver sodium-dependent bile acid cotransporter gene by prolactin. *J. Clin. Invest.* 99:2906-2914.

15. Rangwala, S.M., **O'Brien, M. L.**, Tortorella, V., Longo, A., Loiodice, F., Noonan, D. J. and Feller, D. R. 1997 Stereoselective effects of chiral clofibric acid analogs on rat peroxisome proliferator-activated receptor alpha (rPPAR alpha) activation and peroxisomal fatty acid beta-oxidation. *Chirality* 9:37-47.
16. Feller, D. R., **O'Brien, M**., Rangwala, S. M., Tortorella, V., Loiodice, F. and Noonan, D. J. 1996 Structural requirements of chiral clofibric acid analogs for activation of the rat peroxisome proliferator-activated receptor alpha. *Ann. N. Y. Acad. Sci*. 804:713-715.
17. **O'Brien, M. L.**, Rangwala, S. M., Henry, K. W., Weinberger, C., Crick, D. C., Waechter, C. J., Feller, D. R. and Noonan, D. J. 1996 Convergence of three steroid receptor pathways in the mediation of nongenotoxic hepatocarcinogenesis. *Carcinogenesis* 17:185-190.
18. Henry, K., **O'Brien, M. L.**, Clevenger, W., Jow, L. and Noonan, D. J. 1995 Peroxisome proliferator-activated receptor response specificities as defined in yeast and mammalian cell transcription assays. *Toxicol. Appl. Pharmacol*. 132:317-324.
19. Espandiari, P., Thomas, V. A., Glauert, H. P., **O'Brien, M.**, Noonan, D. J. and Robertson, L. W. 1995 The herbicide dicamba (2-methoxy-3,6-dichlorobenzoic acid) is a peroxisome proliferator in rats. *Fundam. Appl. Toxicol.* 26:85-90.

BOOK CHAPTERS/REVIEW ARTICLES

1. Glauert, H.P., Calfee-Mason, K., Li, Y., Nilakantan, V., **Twaroski, M**., Tharappel, J., and Spear, B.The Role of NF-κB in PPARα-Mediated Carcinogenesis. 2008. *PPAR Research* – invited review Volume 2008 (2008).
2. Bailey, A.,Batarseh, L., Begley, T. and **Twaroski, M.** US FDA Food Contact Materials Regulations. Plastics Packaging Interactions with Food and Pharmaceuticals, Wiley Press (2008) Otto G. Piringer and Albert L. Baner (Eds.).
3. **Twaroski, M.L.,** Batarseh, L.I., and Bailey, A.B. The Regulation of Food Contact Substances in the United States. Chemical Migration and Food Contact Materials. Woodhead Publishing (2007) Barnes, Sinclair, and Watson (Eds.).
4. **O'Brien, M.L.,** Spear, B.T. and Glauert, H.P. 2005 Role of Oxidative Stress in Peroxisome Proliferator-Mediated Carcinogenesis. *Critical Reviews in Toxicology* 35:61-88.
5. Noonan, D.J., Henry, K., and **Twaroski, M.L.** A High Throughput Mammalian Cell-Based Transient Transfection Assay. *In*: Signal Transduction Protocols. Humana Press (2004) Dickson, R.C. and Mendenhall, M.D. (Eds.).
6. Noonan, D.J., Howard, W.R., Yuan, X., and **O'Brien, M.L**. Convergence of Multiple Nuclear Receptor Signaling Pathways in the Mediation of Xenobiotic-Induced Nongenotoxic Carcinogenesis. *In:* Comprehensive Toxicology: VOLUME XIV: Cellular And Molecular Toxicology. Elsevier Publishing (2002) Vanden Heuvel, JP, Perdew, GH, Mattes, WB, and Greenlee, WF (Eds.).

OTHER – PUBLISHED REGULATORY DOCUMENTS

DOCKET FDA-2010-N-0100-0001:
Co-author: Draft Assessment of Bisphenol for use in food contact applications (08/08)
Co-author: Memorandum dated 08/31/2009: Bisphenol A, Review of Low Dose Studies
Co-author: Memorandum dated 11/24/2009: Bisphenol A, update regarding studies added to "Review of low dose assessment"

PUBLISHED ABSTRACTS

1. Kluever, A and **Twaroski, M**. Pilot analysis of food contact notification outcome. 51st Annual Meeting of the Society of Toxicology (accepted, Abstract Number/Poster Board number: 1859 Poster Board - 147) March, 2012, San Francisco, CA
2. Mayer, J, Cheeseman, MA, and **Twaroski, ML.** Structure Activity Relationship Analysis Tools: Validation and Applicability. 2006 FDA Science Forum Board Number: D-23.

3. Arvidson, KB, Benz, R, Matthews, EJ, Mayer, Lee, JE, **Twaroski, ML**, and Yang, C. The Creation of Consolidated FDA Databases and the Development of Real-Time Data Entry to Support Structure Activity Relationship Approaches in Hazard Identification and Risk Assessment. Presented at the 2006 45th Annual Meeting of The Society of Toxicology #905 and the 2006 FDA Science Forum Board Number I-01.
4. Arvidson, KB, Mayer, J, **Twaroski, ML,** Benz, RD, Matthews, EJ, Kruhlak, NL, Cheeseman, MA. Yang, C. Making FDA toxicity data available to the public: FDA ToxML database for genetic toxicity. 2005 229th ACS National Meeting #68.
5. Nelson, C., Mayer, J., Arvidson, K., McDougal, A., Lee, E., and Twaroski, M. Development of a Structurally Searchable Subchronic Studies Database for Use in Predictive Toxicology Modeling. 2005 FDA Science Forum Board B-04
6. Mayer J., Cheeseman, M., Nelson, C., Benz, R., Matthews, E., Kruhlak, N, Contrera, J, **Twaroski, M**., Arvidson, K., and Yang, C. Database Consolidation Based on ToxML of Genetic Toxicity Data Submitted to CFSAN/OFAS and CDER. 2005 44th Annual Meeting of The Society of Toxicology #2204
7. McDougal, A., Cheeseman, M., and **Twaroski, M.**. Integration of FDA databases to develop methodologies for predictive toxicology. 2005 44th Annual Meeting of The Society of Toxicology #1317
8. Mayer, JN, Lo, O, Cheeseman, MA, Nelson, CP, Benz, RD, Matthews, EJ, Kruhlak, NL, Contrera. JF, Yang, C, and **Twaroski, ML.** Database Consolidation of Significant Toxicological Data from Genetic Toxicity Studies Submitted to CFSAN/OFAS and CDER. 2004 FDA Science Forum Board D-29
9. McDougal A, **Twaroski, M**, Chanderbhan, R, Braier, N, Arvidson, K, Mayer, J, Cheeseman, M, and A. Bailey. The use of structure activity relationship (SAR) analysis in the safety assessment of food contact notifications. 2004 43th Annual Meeting of The Society of Toxicology #1021
10. Cheeseman, MA, Bailey, AB, Braier, N C, Chanderbhan, R F, Machuga, EJ, Sheu, CJ and **Twaroski, ML**. 2002 The use of structure activity analysis and genotoxicity testing in the safety evaluation of food contact substances 2002 FDA Science Forum Board AC-12
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