

CURRICULUM VITAE

Paul Brent Watkins, M.D.

Howard Q. Ferguson Distinguished Professor of Pharmacy
Eshelman School of Pharmacy
Professor of Medicine and Public Health
Director, Institute for Drug Safety Sciences
University of North Carolina at Chapel Hill
January 16, 2019

PERSONAL INFORMATION:

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EDUCATION:

Cornell Medical College, New York, NY 1975-1979
Degree: M.D.

Cornell University, Ithaca, NY, 1971-1975
Degree: B.A.
Major: Physical Chemistry

Burnt Hills - Ballston Lake Senior High, Ballston Town, NY, 1968-1971

POSTDOCTORAL TRAINING:

Fellowship (Gastroenterology/Hepatology) 7/82 - 7/84

Research Fellow 7/83 -7/84
NIH Training Grant
Medical College of Virginia,
Division of Environmental Medicine and Clinical Toxicology

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Clinical Fellow 7/82-7/83
Medical College of Virginia,
McGuire Veterans Administration Medical Center

Special Experience
Admission Ward Physician - 4/82 - 7/82
Khao-I-Dang Cambodian Refugee Camp, Thailand

Residency (Internal Medicine)
The New York Hospital - Cornell Medical Center - 7/80-7/82

Internship (Internal Medicine)
The New York Hospital - Cornell Medical Center - 7/79 - 7/80

CERTIFICATION AND LICENSURE:

Medical Licensure: Michigan #050421
North Carolina #99-0163

Board Certification: Internal Medicine, 1982
Gastroenterology, 1984

NPPES NPI Registry: 1386705366

PROFESSIONAL EXPERIENCE - ACADEMIC APPOINTMENTS:

University of North Carolina
Howard Q. Ferguson Distinguished Professor of Pharmacy 7/1/2016 – present
Director, UNC School of Pharmacy Institute for Drug Safety Sciences 9/1/08 - present
Professor of Experimental Therapeutics (School of Pharmacy) - 8/1/99 – present
Verne S. Caviness Distinguished Professor of Medicine – 8/1/99 – 7/1/11
Professor of Medicine (School of Medicine) – 8/1/99 – present
Professor of Toxicology (School of Public Health) – 5/1/07 – present
Director, General Clinical Research Center- 8/1/99 – 5/19/08
Director, Translational and Clinical Sciences Institute – 1/15/07 – 9/1/08

University of Michigan
Professor of Pharmacology - 9/1/98- 7/31/99
Professor of Medicine - 9/1/97 – 7/31/99
Director, General Clinical Research Center - 6/1/91 – 7/31/99
Associate Professor of Medicine - 6/91 – 7/31/99
Associate Director, Clinical Research Center - 3/1/91 - 6/1/91
Assistant Professor of Medicine - 8/86 - 6/91

Medical College of Virginia
Assistant Professor of Medicine - 7/85 - 7/86
Instructor - Department of Medicine - 7/84 - 7/86

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HONORS AND AWARDS:

2018 The American Society of Pharmacology and Experimental Therapeutics (ASPET) Division for Toxicology Career Award, presented 4/24/2018

State of the Art Plenary Lecture at the ACoP 8, International Society of Pharmacometrics, 10/16/2017

Keynote Address at the 21st North American ISSX satellite meeting, 9/26/2017

Keynote Address at the 254th National Meeting of the American Chemical Society Division of Chemical Toxicology 8/22/2017

Keynote Address at the World Preclinical Congress 2017, 6/13/2017

State of the Art Plenary Lecture at the American Gastroenterology Association Annual meeting 5/8/17

2016 Society of Toxicology Award: Top Manuscript published in Toxicological Sciences in 2015.

2015 The Rawls-Palmer Progress in Medicine Award from the American Society of Clinical Pharmacology and Therapeutics

Fellow, American Association for the Study of Liver Diseases 2014

“Highly Cited Researcher” - Among most cited authors in pharmacology worldwide 1983-2014 (ISIHighlyCited.com)

Agilent Thought Leader Award # 2636 - 2014

Society of Toxicology Biological Modeling Specialty Section – 2014 Best Biological Modeling Paper

State-of-the-Art-Lecture at the annual meeting of the American Gastroenterology Association, Chicago, 2011

Fellow, American Gastroenterology Association 2009

Sterling Lecture: Tufts University Medical School 2009

O'Doul Visiting Professorship – University of Kansas 2009

Outstanding Published Paper “Advancing the Sciences of Risk Assessment” – Society of Toxicology, 2009

Goldberg Lecture: University of Chicago, 2008

NIH, MERIT Award, 1998-2008

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Association of American Physicians, 2006

"State of the Art" Plenary Lecture, Annual National Clinical Research Meetings 4/28/05

The Burton Shatz Visiting Professor
Washington University, St Louis 6/30/04

Honorary Membership - Society of Toxicologic Pathology – Presented after Key Note
Lecture at 2004 Annual Meeting in Salt Lake City

The Hyman Zimmerman State-of-the-Art Lecture
Annual meeting of the American Association for the Study of Liver Diseases, 11/1/04

Graduate Student Research Prize (1st place, Shefali Malhotra), International Society for
the Study of Xenobiotics bi-annual meeting, Munich, Germany – 2001

Food and Drug Administration Visiting Professor – 2000

Therapeutic Frontiers Lecture Award, American College of Clinical Pharmacy, 1998

Pfizer Visiting Professor in Clinical Pharmacology to Tufts/New England Medical
Center, 1996

1995 Best Manuscript Award - Drug Metabolism and Disposition

Dean's Award to "Highly Meritorious Faculty," 1994

Fellow, American College of Physicians, 1994

American Society for Clinical Investigation, 1993

Veterans Administration Career Development Awards
Associate Investigator, 7/84-7/86
Research Associate, 1/87-1/91

Who's Who of Young Americans, 1990

"One of 10 Best Lecturers", Introductory Clinical Sciences Courses, University of
Michigan Medical School, 1989

Alpha Omega Alpha, 1978

Student Awards:

Graduate Students:

Leah Norona, Graduate student

2017 SOT Board of Publications Best Paper of the Year in Toxicological Sciences:
To be presented at the Society of Toxicology Annual Meeting (2018), San
Antonio, TX

2017 Young Investigator Travel Award for best abstract to attend the AASLD Liver
Meeting, Washington, DC

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- 2016 Editor's Highlight in the December Issue of Toxicological Sciences:
- 2016 In Vitro and Alternative Methods Specialty Section, Second Place Graduate Student Poster Award, Society of Toxicology Annual Meeting, New Orleans, LA
- 2016 Sheldon D. Murphy Student Travel Award for best abstract to attend the Society of Toxicology Annual Meeting, New Orleans, LA
- 2015 FutureTox III Gold Level Award for submission of a meritorious abstract to attend the FutureTox III Meeting, Arlington, VA
- 2015 Leon Goldberg Memorial Travel Award for best abstract to attend the Society of Toxicology Annual Meeting, San Diego, CA
- 2015 Second Place Curriculum in Toxicology Retreat Poster Presentation
- 2013 National Science Foundation Graduate Research Fellowship (NSF-GRF) Honorable Mention
- 2012-2013 Initiative for Maximizing Student Diversity (IMSD) Fellowship

Natalie Holman, Graduate student

- 2015 1st Place, Graduate Student Poster Competition, UNC Curriculum in Toxicology Annual Retreat
- 2015 2nd Place, Poster Competition, SOT North Carolina Regional Chapter Spring Meeting
- 2015 Leon Goldberg Memorial Travel Award, administered by UNC Chapel Hill for the National SOT Annual Meeting
- 2015 1st Place, Platform Presentation, Gordon Research Seminar, Cellular and Molecular Mechanisms of Toxicity
- 2014 UNC-Chapel Hill Graduate Student Nominee, PhRMA Foundation Pre-doctoral Fellowship in Pharmacology & Toxicology
- 2014 1st Place, Graduate Student Poster Competition, UNC-HHMI Translational Medicine Annual Symposium
- 2013 UNC-Chapel Hill Graduate Student Nominee, PhRMA Foundation Pre-doctoral Fellowship in Pharmacology & Toxicology

Shefali Malhotra, Graduate student

- 2001 First place, graduate student presentation at the annual meeting of the International Society for the Study of Xenobiotics

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Postdoctoral Fellows:

Merrie Mosedale, PhD, Postdoctoral Fellow

- 2013 ASPET Postdoctoral Award for Integrative Research in Pharmacology
- 2013 SOT Risk Assessment Specialty Section Perry J. Gehring Best Postdoctoral Fellow Abstract Award
- 2013 SOT Risk Assessment Specialty Section Top 10 Abstract Award
- 2013 SOT Regulatory and Safety Evaluation Specialty Section Travel Award
- 2013 Finalist, SOT Drug Discovery Toxicology Specialty Section Postdoctoral Poster Competition
- 2012 Third Place, North Carolina Society of Toxicology President's Award for Research Competition

Rachel Church, PhD, Postdoctoral Fellow

- 2014 NIH-funded T32 UNC-Duke-Hamner Collaborative Clinical Pharmacology Fellowship
- 2014 SOT Emil A. Pfitzer Drug Discovery Postdoctoral Poster Competition- Second Place
- 2014 SOT Perry J. Gehring Postdoctoral Risk Assessment Award
- 2013 SOT Emil A. Pfitzer Drug Discovery Postdoctoral Poster Competition- Second Place
- 2013 SOT Risk Assessment SS John Doull Award
- 2013 RTP Drug Metabolism Discussion Group Winter Symposium - Podium Presentation Award- Second Place

BIBLIOGRAPHY:

Completed publications in scientific journals:

Peer-reviewed journals:

1. Elizabeth T. Cirulli, Paola Nicoletti, Nanye Long, Karen Abramson, Raul J. Andrade, Huiman X. Barnhart, Einar S. Bjornsson, Naga Chalasani, Robert J. Fontana, Pär Hallberg, M Isabel Lucena, Mariam Molokhia, Matthew R. Nelson, Joseph A. Odin, Munir Pirmohamed, Jose Serrano, Yufeng Shen, Andrew Stolz, Thomas J. Urban, Ann K. Daly, Guruprasad P. Aithal and **Paul B. Watkins**, on behalf of Drug-induced liver injury network (DILIN) investigators and International DILI consortium (iDILIC). A Missense Variant in PTPN22 is a Risk Factor for Drug-induced Liver Injury. *Gastroenterology* (2019) Jan 13 [Accepted].
2. Leah M. Norona, Deborah G. Nguyen, David A. Gerber, Sharon C. Presnell, Merrie Moesdale, and **Paul B Watkins**. Bioprinted liver provides early insight into the role of Kupffer cells in TGF-B1 and methotrexate-induced fibrogenesis. *PLOS One* (2019) January; 14(1).
3. Elizabeth J. Baker, Nancy A. Beck, Ellen L. Berg, Helene D. Clayton-Jeter, P. Charukeshi Chandrasekera, J. Lowry Curley, Bruce A. Donzanti, Lorna C. Ewart, Jane M. Gunther, J. Gerry Kenna, Edward L. LeCluyse, Michael N. Liebman, Catherine L. Pugh, **Paul B. Watkins**, and Kristie M. Sullivan. Advancing nonclinical innovation and safety in pharmaceutical testing. *Drug Discovery* (2018) Nov 20 [Epub before print].
4. Diane Longo, Jeffrey L. Woodhead, Paul Walker, Krisztina Heredi-Szabo, Karoly Mogyorosi, Francis Wolenski, Yvonne Dragan, Merrie Mosedale, Scott Q. Siler, **Paul B. Watkins**, Brett A. Howell. Quantitative Systems Toxicology Analysis of In Vitro Mechanistic Assays Reveals Importance of Bile Acid Accumulation in TAK-875-induced Liver Injury. *Tox Sci* (2018) Oct 5 [Epub before print].
5. Rachel J Church, **Paul B Watkins**. Serum biomarkers of drug-induced liver injury: Current status and future directions. *J Dig Dis* (2018) October 30 [Epub before print]. Review.
6. Chung, JY, Longo, D, **Watkins, PB**. A Rapid Method to Estimate Hepatocyte Loss due to Drug-induced Liver Injury. *CPT* (2018) October 10 [Epub before print].
7. Robert John Fontana, Elizabeth T Cirulli, Jiezhun Gu, David Kleiner, David Ostrov, Elizabeth Phillips, Ryan Schutte, Huiman Barnhart, Naga Chalasani, **Paul Brent Watkins**, Jay H. Hoofnagle. The role of HLA-A*33:01 in patients with cholestatic hepatitis attributed to terbinafine. *Hepatology* (2018) August 21 [Epub before print].
8. Christina Battista, Kyunghee Yang, Simone Stahl, Jerome Mettetal, **Paul B Watkins**, Scott Q Siler, Brett A Howell. Using quantitative systems to investigate

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- observed species differences in CKA-mediated hepatotoxicity. *Toxicol Sci.* (2018) Nov 1;166(1):123-130.
9. Bonkovsky HL, Barnhart HX, Foureau DM, Steuerwald N, Lee WM, Gu J, Fontana RJ, Hayashi PJ, Chalasani N, Navarro VM, Odin J, Stolz A, **Watkins PB**, Serrano J. Cytokine profiles in acute liver injury-Results from the US Drug-Induced Liver Injury Network (DILIN) and the Acute Liver Failure Study Group. *PLoS One.* 2018 Oct 25;13(10):e0206389.
 10. J Kenna, Kunal Taskar, Christina Battista, David Bourdet, Kim Brouwer, Kenneth Brouwer, David Dai, Christoph Funk, Michael Hafey, Yurong Lai, Jonathan Maher, Y Pak, Jenny Pedersen, Joseph Polli, A. Rodrigues, **Paul Watkins**, Kyunghee Yang, and Robert Yucha. Can BSEP Inhibition Testing in Drug Discovery and Development Reduce Liver Injury Risk? - An International Transporter Consortium Perspective. *Clin Pharmacol Ther.* 2018 Nov;104(5):916-932. Review.
 11. Jeffrey Woodhead, Franziska Paech, Martina Maurer, Marc Engelhardt, Anne-Hortense Schmitt-Hoffmann, Jochen Spickermann, Simon Messner, Mathias Wind, Anne Witschi, Stephan Krabenbuhl, Scott Siler, **Paul Watkins**, and Brett Howell. Prediction of Safety Margin and Optimization of Dosing Protocol for a Novel Antibiotic using Quantitative Systems Pharmacology Modeling. *Clin Transl Sci* (2018) Sept; 11(5):498-505.
 12. **Watkins, PB.** Improving Interpretation of new and old serum biomarkers of drug-induced liver injury through mechanistic modeling. Commentary. *CPT: Pharmacometrics Syst. Pharmacol.* 2018 Jun;7(6):356-359. doi:10.1002/psp4.12303.
 13. Marcinak, JF, Munsaka, MS, **Watkins, PB**, Ohira, T, Smith. Liver Safety of Fasigliam (TAK-875) in Patients with Type 2 Diabetes: Review of the global clinical trial experience. *Drug Safety.* 2018 Jun; 41(6):625-640.
 14. Thacker, SE, Nautiyal, M, Otieno, M, **Watkins, PB**, Mosedale, M. Optimized Methods to Explore the Mechanistic and Biomarker Potential of Hepatocyte-Derived Exosomes in Drug-Induced Liver Injury. *Toxicol. Sci.* 2018 May 1;163(1):92-100. PMID: 29385596
 15. Church, RJ, Kullak-Ublick, GA, Aubrecht, J, Bonkovsky, HL, Chalasani, N, Fontana, RJ, Goepfert, JC, Hackman, F, King, NMP, Kirby, S, Kirby, P, Marcinak, J, Ormarsdottir, S, Schomaker, SJ, Schuppe-Koistinen, I, Wolenski, F, Arber, N, Merz, M, Sauer, JM, Andrade, RJ, van Bömmel, F, Poynard, T, **Watkins, PB.** Candidate biomarkers for the diagnosis and prognosis of drug-induced liver injury: an international collaborative effort. *Hepatology.* 2018 Jan 22 [Epub before print]. PMID: 29357190
 16. Mosedale, M, Button, D, Jackson, JP, Freeman, KM, Brouwer, KR, Caggiano, AO, Eisen, A, Iaci, JF, Parry, TJ, Stanulis, R, Srinivas, M, **Watkins, PB.** Transient Changes in Hepatic Physiology That Alter Bilirubin and Bile Acid Transport May Explain Elevations in Liver Chemistries Observed in Clinical Trials of GGF2 (Cimaglermin alfa). *Toxicol Sci.* 2018 Feb 1;161(2):401-411. PMID: 29069498
 17. Mosedale, M, Eaddy, J, Trask, OJ Jr, Holman, NS, Wolf, KK, LeCluyse, E, Ware, BR, Khetani, SR, Lu, J, Brock, WJ, Roth, SE, **Watkins, PB.** miR-122 Release in

- Exosomes Precedes Overt Tolvaptan-Induced Necrosis in a Primary Human Hepatocyte Micropatterned Coculture Model. *Toxicol Sci.* 2018 Jan 1;161 (1):149-158. PMID: 29029277
18. Tikunov, AP, Shim, YS, Bhattarai, N, Siler, S, Soldatow, V, LeCluyse, E, McDunn, JE, **Watkins, PB**, Macdonald, JM. Dose-Response in a High Density Three-Dimensional Liver Device with Real-Time Bioenergetic and Metabolic Flux Quantification. *Toxicol in Vitro.* 2017 Dec;45(Pt 1):119-127. PMID: 28867505
 19. Church, RJ, **Watkins, PB**. In silico modeling to optimize interpretation of liver safety biomarkers in clinical trials. *Exp Biol Med.* 2018 Feb;243(3):300-307. PMID: 29096561. (Review).
 20. Longo, DM, Generaux, G, Howell, BA, Siler, SQ, Antoine, DJ, Button, D, Caggiano, A, Eisen, A, Iaci, J, Stanulis, R, Mosedale, M, **Watkins, PB**. Refining Liver Safety Risk Assessment: Application of Mechanistic Modeling and Serum Biomarkers to Cimagermin alfa (GGF2) Phase 1 Clinical Trials. *CPT.* 2017 102(6): 961-969. PMID: 28419467
 21. Howell, BA, Siler, SQ, Barton, HA, Joshi, EM, Cabal, A, Eichenbaum, G, **Watkins, PB**. Development of Quantitative Systems Pharmacology and Toxicology Models within Consortia: Experiences and Lessons Learned Through DILIsym Development. *Drug Disc Today.* 2017 Nov; 22: 5-13. <http://dx.doi.org/10.1016/j.ddmod.2017.04.001>
 22. Urban, TJ, Nicoletti, P, Chalasani, N, Serrano, J, Stolz, A, Daly, AK, Aithal, GP, Dillon, JF, Navarro, VJ, Odin, JA, Barnhart, HX, Ostrov, DA, Long, N, **Watkins, PB**, Fontana, RJ. Minocycline Hepatotoxicity: Clinical characterization and identification of HLA-B* 35:02 as a risk factor. *J of Hepatology.* 2017 Jul;67(1):137-144. PMID: 28323125
 23. Church RJ, **Watkins PB**. The transformation in biomarker detection and management of drug-induced liver injury. *Liver Int.* 2017 Nov; 37(11):1582-1590. Review. PMID: 28386997. (Review).
 24. Mosedale, M, **Watkins, PB**. Drug-Induced Liver Injury: Advances in Mechanistic Understanding that will Inform Risk Management. *Clin Pharmacol Ther.* 2017 Apr; 101(4):469-480. Review. PMID: 27861792. (Review).
 25. Shoda, LK, Battista, C, Siler, SQ, Pisetsky, DS, **Watkins, PB**, Howell, BA. Mechanistic Modelling of Drug-Induced Liver Injury: Investigating the Role of Innate Immune Responses. *Gene Regul Syst Bio.* 2017 May; 11:1-20. PMID: 28615926
 26. Yang, K, Battista, C, Woodhead, JL, Stahl, SH, Mettetal, JT, **Watkins, PB**, Siler, SQ, Howell, BA. Systems Pharmacology Modeling of Drug-Induced Hyperbilirubinemia: Differentiating Hepatotoxicity and Inhibition of Enzymes/Transporters. *Clin Pharmacol Ther.* 2017 Apr;101(4):501-509. PMID: 28074467
 27. Nicoletti, P, Aithal, GP, Bjornsson, ES, Andrade, RJ, Sawle, A, Arrese, M, Barnhart, HX, Bondon-Guitton, E, Hayashi, PH, Bessone, F, Carvajal, A, Cascorbi, I, Cirulli, ET, Chalasani, N, Conforti, A, Coulthard, SA, Daly, MJ, Day, CP, Dillon, JF, Fontana, RJ, Grove, JI, Hallberg, P, Hernández, N, Ibáñez, L,

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- Kullak-Ublick, GA, Laitinen, T, Larrey, D, Lucena, DMI, Maitland-van der Zee, AH, Martin, JH, Molokhia, M, Pirmohamed, M, Powell, EE, Qin, S, Serrano, J, Stephens, C, Stolz, A, Wadelius, M, **Watkins, PB**, Floratos, A, Shen, Y, Nelson, MR, Urban, TJ, Daly, AK. Association of Liver Injury from Specific Drugs, or Groups of Drugs, With Polymorphisms in HLA and Other Genes in a Genome-wide Association Study. *Gastroenterology*. 2017 Apr; 152(5):1078-1089. PMID: 28043905
28. Mosedale, M, Kim, Y, Brock, WJ, Roth, SE, Wiltshire, T, Eaddy, S, Keele, GR, Corty, RW, Xie, Y, Valdar, W, **Watkins, PB**. Candidate risk factors and mechanisms for Tolvaptan-Induced liver injury are identified using a collaborative cross approach. Editor's Choice. *Toxicol Sci*. 2017 Apr 1; 156 (2):438-454. PMID: 2811565
29. Russo, MW, Steuerwald, N, Norton, HJ, Andersen, WE, Foureau, D, Chalasani, N, Fontana, RJ, **Watkins, PB**, Serrano, J, Bonkovsky, HL. Profiles of miRNAs in Serum in Severe Acute Drug Induced Liver Injury and their Prognostic Significance. *Liver Int*. 2017 May; 37(5):757-764. PMID: 27860186
30. Woodhead, JL, **Watkins, PB**, Howell, BA, Siler, SQ, Shoda, LK. The Role of Quantitative Systems Pharmacology Modeling in the Prediction and Explanation of Idiosyncratic Drug-Induced Liver Injury. Review. *Drug Metab and Pharmacokinet*. 2017 Feb; 32(1):40-45. PMID: 28129975
31. Woodhead, JL, Brock, WJ, Roth, SE, Shoaf, SE, Brouwer, KL, Church, R, Grammatopoulos, TN, Stiles, L, Siler, SQ, Howell, BA, Mosedale, M, **Watkins, PB**, Shoda, LK. Application of a Mechanistic Model to Evaluate Putative Mechanisms of Tolvaptan Drug-Induced Liver Injury and Identify Patient Susceptibility Factors. *Toxicol Sci*. 2017 Jan; 155(1): 61-74. PMID: 27655350
32. Mikus, M, Drobin, K, Gry, M, Bachmann, J, Lindberg, J, Yimer, G, Aklillu, E, Makonnen, E, Aderaye, G, Roach, J, Fier, I, Kampf, C, Göpfert, J, Perazzo, H, Poynard, T, Stephens, C, Andrade, RJ, Lucena, MI, Arber, N, Uhlén, M, **Watkins, PB**, Schwenk, JM, Nilsson, P, Schuppe-Koistinen, I. Elevated levels of circulating CDH5 and FABP1 in association with human drug-induced liver injury. *Liver Int*. 2017 Jan; 37(1): 132-140. PMID: 27224670
33. Holman, NS, Mosedale, M, Wolf, KK, LeCluyse, EL, **Watkins, PB**. Sub-toxic alterations in hepatocyte-derived exosomes: an early step in drug-induced liver injury? *Tox Sci*. 2016 Jun; 151(2):365-75. PMID: 26962055
34. Bushel, PR, Fannin, RD, Gerrish, K, **Watkins, PB**, Paules, RS. Blood gene expression profiling of an early acetaminophen response. *Pharmacogenomics J*. 2017 Jun; 17(3):230-236. PMID: 26927286
35. Yang, K, Guo, C, Woodhead, JL, St Claire, RL, **Watkins, PB**, Siler, SQ, Howell, BA, Brouwer, KLR. Sandwich-Cultured Hepatocytes as a Tool to Study Drug Disposition and Drug-Induced Liver Injury. *Journal of Pharmaceutical Sci*. 2016 Feb; 105(2):443-459. PMID: 26869411. Review.
36. Longo, DM, Yang, Y, **Watkins, PB**, Howell, BA, Siler, SQ. Elucidating Differences in the Hepatotoxic Potential of Tolcapone and Entacapone with DILIsym, a

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- Mechanistic Model of Drug-Induced Liver Injury. CPT Pharmacometrics System. Pharmacol. 2016 Jan; 5(1):31-9. PMID: 26844013 PMCID: PMC4728295
37. Fannin, R, Gerrish, K, Sieber, S, Bushel, P, **Watkins, PB**, Paules, R. Blood transcript immune signatures distinguish a subset of people with elevated serum ALT from others given acetaminophen. Clinical Pharma & Ther. 2016 Apr; 99(4):432-41. PMID: 26690555
 38. Church, RJ, Otieno, M, McDuffie, JE, Singh, B, Sonee, M, Hall, L, **Watkins, PB**, Ellinger-Ziegelbauer, H, Harrill, AH. Beyond miR-122: Identification of microRNA alterations in blood during a time course of hepatobiliary injury and biliary hyperplasia in rats. Toxicol Sci. 2015 Mar; 150(1):3-14. PMID: 26614776
 39. Goldring, C, Norris, A, Kitteringham, N, Aleo, MD, Antoine, DJ, Heslop, J, Howell, BA, Ingelman-Sundberg, M, Kia, R, Kamalian, L, Koerber, S, Martinou, J, Mercer, A, Moggs, J, Naisbitt, DJ, Powell, C, Sidaway, J, Sison-Young, R, Snoeys, J, Van de Water, B, **Watkins, PB**, Weaver, RJ, Wolf, A, Zhang, F, Park, BK. Mechanism-Based markers of drug-induced liver injury to improve the physiological relevance and predictivity of in vitro models. Applied in vitro toxicology. 2015; 1(3).
 40. Fontana, RJ, Hayashi, PH, Barnhart, H, Kleiner, DE, Reddy, KR, Chalasani, N, Lee, WM, Stolz, A, Phillips, T, Serrano, J, **Watkins, PB**. Persistent Liver Biochemistry Abnormalities Are More Common in Older Patients and those With Cholestatic Drug Induced Liver Injury. Am J Gastroenterol. 2015 Oct; 110(10):1450-9. PMID: 26346867
 41. **Watkins, PB**, Lewis, JH, Kaplowitz, N, Alpers, DH, Blais, JD, Smotzer, DM, Krasa, H, Ouyang, J, Torres, VE, Czerwiec, FS, Zimmer, CA. Clinical Pattern of Tolvaptan-Associated Liver Injury in Subjects with Autosomal Dominant Polycystic Kidney Disease: Analysis of Clinical Trials Database. Drug Saf. 2015 Nov; 38(11):1103-13. PMC4608984
 42. Lu, J, Einhorn, S, Venkatarangan, L, Miller, M, Mann, DA, **Watkins, PB**, LeCluyse, E. Morphological and Functional Characterization and Assessment of iPSC-derived Hepatocytes for In Vitro Toxicity Testing. Toxicol Sci. 2015 Sep; 147(1):39-54. PMID: 26092927
 43. Chalasani, N, Bonkovsky, HL, Fontana, R, Lee, W, Stolz, A, Talwalkar, J, Reddy, KR, **Watkins, PB**, Navarro, V, Barnhart, H, Gu, J, Serrano, J, DILIN. Features and Outcomes of 889 Patients with Drug-induced Liver Injury: The DILIN Prospective Study. Gastroenterology. 2015 June; 148(7):1340-1352. PMID: 25754159; PMC4446235
 44. **Watkins, PB**. How to diagnose and exclude DILI. Digestive Diseases. 2015 July; 33(4):472-476. PMID: 26159261
 45. Yang, Y, Nadanaciva, S, Will, Y, Woodhead, JL, Howell, BA, **Watkins, PB**, Siler, SQ. MITOsym®: A mechanistic, mathematical model of hepatocellular respiration and bioenergetics. Pharm Res. 2015 Jun; 32(6):1975-92. PMID: 25504454 PMCID: PMC4422870

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47. Woodhead, JL, Yang, K, Siler, SQ, **Watkins, PB**, Brouwer, KLR, Barton, HA, Howell, BA. Exploring BSEP Inhibition-Mediated Toxicity with a Mechanistic Model of Drug-Induced Liver Injury. *Front Pharmacol.* 2014 Nov 7; 5:240. PMID: 25426072 PMCID: PMC4224072
48. Foureau, D, Walling, T, Maddukuri, V, Anderson, W, Kleiner, D, Ahrens, W, Jacobs, C, **Watkins, PB**, Fontana, RJ, Chalasani, N, Talwalker, JA, Lee, WM, Stolz, A, Serrano, J, Bonkovsky, H. Comparative analysis of portal hepatic infiltrating leukocytes in acute drug-induced liver injury, idiopathic autoimmune and viral hepatitis. *Clin Exp Immunol.* 2015 Apr; 180(1):40-51. PMID: 25418487
49. Knudsen, TB, Keller, DA, Sander, M, Carney, EW, Doerrer, NG, Eaton, DL, Fitzpatrick, SC, Hastings, KL, Mendrick, DL, Tice, RR, **Watkins, PB**, Whelan, M. FutureTox II: *In vitro* data and *in silico* models for predictive toxicology. *Toxicol Sci.* 2015 Feb; 143(2):256-267. PMID: 25628403
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28. **Watkins, P.B.** Drug metabolism by cytochromes P450 in liver and small bowel. In *Gastroenterology Clinics of North America* (Ed) William Stetson. 21(3):511-525, 1992. (Book chapter).
29. **Watkins, P.B.** "Pharmacology of the Gut." In: *Textbook of Gastroenterology*, ed. T. Yamada (Lippincott, 1991), 518-531. (Book chapter).
30. **Watkins, P.B.** "The role of cytochromes P-450 in drug metabolism and hepatotoxicity." In: *Seminars in Liver Diseases, Recent Advances in Drug Metabolism and Hepatotoxicity*, ed. N. Kaplowitz 1990; 10 (4):235-250. (Book chapter).
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32. **Watkins, P.B.**, Bond, J., Guzelian, P.S. "Degradation of the Hepatic Cytochromes P-450". In: Critical Reviews in Biochemistry, the Mammalian Cytochromes P-450, ed. F.P. Guengerich (CRC Press, 1987), Ch. 6, 173. (Book chapter).

INVITED TALKS AND NATIONAL AND INTERNATIONAL MEETINGS:

1. 11/11/2018 – AASLD Meeting
San Francisco, CA
Abstract accepted: Identification of a PTPN22 Missense Variant As a General Genetic Risk Factor for Drug-Induced Liver Injury
Oral Presentation by Paola Nicoletti, MD, PhD
2. 11/7/2018 – AAPS PharmaSci 360
Washington, DC
Invited Speaker: Mechanisms Underlying Species Differences in Hepatotoxicity
3. 5/22-5/23/2018 – NIH NCATS Translator May Hackathon
Invited SME (Subject Matter Expert) on DILI
Bethesda, MD
4. 4/24/18 - ASPET 2018 Annual Meeting
San Diego, CA
Presented with the Division for Toxicology Career Award
5. 2/8/2018 - The FDA Pharmacology/Toxicology Coordinating Committee (PTCC) Education Subcommittee
Silver Springs, MD
Invited Speaker: Using Quantitative Systems Toxicology (QST) to Assess Drug Safety: The Experience of the DILI-sim Initiative
6. 1/30/2018 – Toxicology Forum 42nd Annual Winter Meeting
Washington, DC
Invited Speaker: Cross-Sector Partnerships as a Driver for Liver Toxicity Modeling Platform DILIsym
7. 10/20/2017 – AASLD Hepatotoxicity Special Interest Group (SIG) Symposium at the 2017 Liver meeting
Washington, DC
Co-moderator: Controversial Issues – Clinical Cases, Monitoring, and Regulatory Issues.
8. 10/16/2017 – International Society of Pharmacometrics ACoP 8 meeting
Fort Lauderdale, FL
State of the Art Lecture: Using Quantitative Systems Toxicology (QST) to Assess Drug Safety: The Experience of the DILI-sim Initiative
9. 9/26/2017 - 21st North American ISSX meeting, HRA meeting
Providence, RI
Keynote Speaker: Quantitative Systems Toxicology and DILI: Where do culture models fit in?

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10. 8/22/2017- 254 American Chemical Society National Meeting
Washington, DC
Key Note Speaker: Understanding hepatotoxicity: Man to mouse to computer
11. 7/11/2017 – Drug Discovery and Therapy World Congress
Boston, MA
Session Lecture: Using Quantitative Systems Toxicology (QST) to Assess Drug Safety: The Experience of the DILI-sim Initiative
12. 6/13/2017 – World Preclinical Congress
Boston, MA
Invited Speaker: Predicting Liver Safety Liabilities in New Drug Candidates: Are We There Yet?
13. 6/6/2017 – FDA C-Path DILI Conference XVII
Bethesda, MD
Meeting Organizer and Invited Speaker: DILIsym Initiative
14. 5/8/2017 – AASLD at Digestive Disease Week
Chicago, IL
State of the Art Lecture: DILI: Is this Pill Safe to Swallow?
15. 2/18/2017 – APASL 2017- Asian Pacific Association for the Study of the Liver
Shanghai, China
Invited speaker: Drug Induced Liver Disease and Liver Protection - The Search for Better Serum Biomarkers of DILI
Chair of Session: Oral Presentation 16 - Drug induced Liver Disease and Liver Failure
16. 1/11/2017 – “Preclinical Innovation and Patient Safety Roundtable,” hosted by Physicians Committee for Responsible Medicine
Washington, DC
Invited Speaker: The DILI-sim Initiative
Invited member of panel: Identifying and Discussing Educational/Training Opportunities to Improve Preclinical Testing
17. 1/9/2017 – FDA NCTR: The Liver Toxicity Working Group Workshop
Little Rock, AR
Topic: Drug-Induced Liver Injury: Cross-Talk among Clinicians, Toxicologists, and Regulators
Invited speaker via WebEx: “Quantitative Systems Toxicology Approaches to Assess Liver Safety”
18. 12/7/2016 – QSP 2016
San Francisco, CA
Invited Speaker: QSP Modeling of Hepatotoxicity: Understanding & Predicting Dose Dependent & Idiosyncratic Events
Panel discussion leader: Combining QSP with Systems Toxicology
Workshop leader: Lessons learnt from pre-competitive consortia & other open innovation partnerships to bridge drug discovery & development
19. 11/16/2016 – World Preclinical Congress Europe
Lisbon, Portugal
Keynote Presentation: Using Quantitative Systems Toxicology (QST) to Assess and Manage Drug Safety

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Moderator of Panel Discussion: Breaking Down Silos: Updates on New Initiatives, Consortia & Collaborations

20. 7/14/16 - FDA Critical Path Institute PSTC BSEP Webinar Series - Current Trends in BSEP Inhibition and Perturbation to Bile Acid Homeostasis as Mechanisms of Drug-Induced Liver Injury
Chair of Webinar 6: Future Direction
21. 7/3/16 - 2016 Sino-America International Symposium on Drug Induced Liver Injury, And, the 3rd National Conference of Drug Induced Liver Injury
Shanghai, China
Invited Speaker: DILI in US - Researches from the US DILIN Network
Invited Speaker: Hot topic and outlook in the field of DILI research
22. 6/29/16 - Gordon Research Conference: Improving Drug Safety: From Innovation in the Lab to Application in the Clinic
Easton, MA
Invited Speaker: "Modeling Idiosyncratic Hepatotoxicity: Progress and Challenges of DILI-sim Initiative"
23. 4/14 – 4/15/16 - FDA and Foundation for the National Institute of Health “Biomarker Qualification Workshop: Framework for Defining Evidentiary Criteria”
Bethesda, Maryland
Invited Panelist: A Biomarker of Drug-Induced Liver Injury
24. 4/2 – 4/6/16 – ASPET Annual Meeting at – Experimental Biology 2016 – Transforming Discoveries into Therapies
San Diego, CA
Symposium Chair: Modulation of BSEP and MDR3 in Drug-Induced Liver Injury (DILI)
Invited Speaker: Integration of BSEP Inhibition Data in DILIsym®: Perspectives from System
25. 3/23-3/24/16 – FDA Drug-Induced Liver Injury (DILI) Conference XVI: How Should Liver Injury and Dysfunction Caused by Drugs Be Measured, Evaluated, and Acted Upon in Clinical Trials?
East Hyattsville, MD
Co-Organizer of meeting
Session leader: Hot New Research and Clinical Breakthroughs in the DILI Field
Invited Speaker: Application of Novel Biomarkers to Assess Liver Safety in Clinical Trials
26. 3/2/16 – International Meeting on Formation of a Cross-Pharma Drug-Induced Liver Injury Consortium
Washington, D.C.
Invited Speaker: (Remotely) Review of Ongoing efforts of the DILIN Network
27. 10/29/15 – Triangle Biotech Research Symposium IV: Advancing Human Health through Technology Convergence
RTP, NC
Invited Speaker: Converging Technologies: In Silico Approaches to Predicting Drug Induced Liver Injury

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28. 10/26/15 – FDA/Brookings Institute Biomarker Workshop: Facilitating Biomarker Development and Qualification: Strategies for Prioritization, Data-Sharing, and Stakeholder Collaboration
Washington, DC
Invited panelist in Session: Strategies for Improving Data Standardization and Sharing
29. 10/25/15 – 2015 AAPS Annual Meeting and Exposition
Orlando, FL
Session: Short Course 5: Quantitative Translational Safety: A 21st Century Approach for Predictive Assessment of Drug-Induced Hepatic and Renal Toxicities
Invited Speaker: Assessing Drug-Induced Liver Injury during Clinical Trials and Post-Marketing
30. 10/21/15 – 20th North American ISSX Meeting
Orlando, FL
Plenary Speaker: Understanding Idiosyncratic Hepatotoxicity: From Cage to Clinic
31. 10/21/15 – 20th North American ISSX meeting
Orlando, FL
Session: Transporters and Biomarkers in Kidney and Liver-Implications for Drug Development
Invited speaker: Hepatic Biomarkers and the Transformation of Liver Risk Assessment
32. 8/21/15 – FDA, C-Path Symposium: Evidentiary Considerations for Integration of Biomarker in Drug Development
Silver Spring, MD
Invited panelist
33. 6/28/15 – 12th Conference of the European Association for Clinical Pharmacology and Therapeutics (EACPT)
Madrid, Spain
Symposium: Clinical Networks and Consortia in Drug-Induced Liver Injury: an opportunity for advancing Safety Science
Invited Speaker: The DILI-sim Initiative: Integrated systems pharmacology-based to explain and predict drug hepatotoxicity
34. 6/23/15 - 13th European ISSX Meeting
University of Strathclyde
Glasgow, Scotland
Invited Speaker: Systems Modeling Approaches to Predict Idiosyncratic DILI
35. 5/26/15 – Quantitative Systems Pharmacology: Progress Towards Integration into Drug Discovery and Development
New York Academy of Science
New York, NY
Invited Speaker: QSP Modeling to Manage Hepatotoxicity in Drug Development
36. 3/24/2015 - SOT Annual Meeting 2015
San Diego, CA
Workshop Session: Current Understanding of Immune-Mediated Adverse Drug Reactions, Advancing Clinical and Translational Toxicology
Invited Speaker: Drug-Induced Events That Initiate an Adaptive Immune Attack on the Liver

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37. 3/5/2015 – 2015 ASCPT Annual Meeting – Rawls-Palmer Progress in Medicine Award Lecture
New Orleans, LA
Rawls-Palmer Progress in Medicine Award Lecture: Why Good Drugs are Sometimes Bad for the Liver
38. 11/9/2014 – AASLD – The Liver Meeting
Boston, MA
Invited Speaker: GWAS and Exome Chips in DILI: What have we learned?
39. 11/9/2014 – AASLD – The Liver Meeting
Boston, MA
Invited Speaker: Causality Assessment and Autoimmunity in Hepatotoxicity
40. 10/14/2014 – ITMAT 9th Annual International Symposium, Perelman School of Medicine, University of Pennsylvania
Philadelphia, PA
Invited speaker: Why good drugs are sometimes bad for the liver-from man to mouse to computer
41. 10/9/2014 – Falk Workshop, The Challenge of drug-induced liver injury (DILI)
Freiburg, German
Invited speaker: How to diagnose and exclude DILI
42. 9/3/2014 – 9/4/2014 – ADME - Metabolites and Safety - Relating Biotransformation to Human Safety Hazard and Risk: Addressing the Translational Gaps
Gothenburg, Sweden
Invited lecturer: Physiologically based systems modelling of drug induced liver injury
43. 6/21/2014 – 5th Sino-American Symposiums (SAS) on Clinical and Translational Medicine
Beijing, CHINA
Co-chair of Session II: Innovative Drug Research and Development
Invited lecturer: Novel biomarker approaches that will revolutionize risk management of drug-induced liver injury
44. 5/7/2014 – 5/9/2014 – Drug Information Association - Drug Induced Organ Injury of Liver, Heart, Kidney, and Skin: Employing recent advances to improve patient safety and speed up the pipeline
Bethesda, MD
Meeting co-organizer
Session chair: DILI in Clinical Trials and Post Marketing
Presentation: The Future
Invited Panelist: Emerging Cross-cutting Approaches to Assessment of Drug Safety
45. 3/24/2014 SOT Annual Meeting 2014
Phoenix, AZ
Cellular Dynamics symposium session: Induced Human Pluripotent Stem Cells and Their Differentiated Progeny Cells: Implementation in Toxicity Testing
Invited Speaker: iPSC-Derived Liver Cultures to Study Mechanisms Underlying Idiosyncratic Hepatotoxicity

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46. 3/19/2014 – 3/20/2014 – FDA DILI Conference XIV Predicting Serious Drug-Induced Liver Injury in Patients
Hyattsville, MD
Meeting co-organizer
Invited Speaker: Academic research breakthroughs – Will biomarkers do it?
Session Moderator: What new and useful biomarkers (and predictors) are out there?
Invited Speaker: Lessons from healthy volunteers
47. 1/16/2014 – 1/17/2014 – SOT Future Tox II Meeting: *In Vitro* Data and *In Silico* Models for Predictive Toxicology
Chapel Hill, NC
Meeting co-organizer: Future Tox II Planning Committee
Breakout Group Leader: Liver disease and hepatotoxicity
48. 11/3/2013 – 11/4/2013 - AASLD The Annual National Meeting
Washington, DC
Meet the professor Breakfast Seminar: Invited Speaker: Are Patients with Chronic Liver Disease at Greater Risk of Drug-Induced Liver Injury?
49. 11/3/2013 – 11/4/2013 - AASLD The Annual National Meeting 2013
Washington, DC
Invited Plenary Speaker: Update on General Hepatology: Recent advances in Drug-Induced Liver Injury
50. 10/2/2013 – 10th International ISSX Meeting
Toronto, CA
Invited Speaker: Insights from Healthy Volunteer Studies
51. 9/26/13 – FDA – Critical Path Institute Modeling and Simulation for Medical Products Workshop
Invited Speaker: Collaborative Approaches to Mechanistic Modeling *and* workshop participant
52. 9/17/13 – MRC Centre for Drug Safety Science, University of Liverpool “In Vitro Endpoints and Markers of Hepatotoxicity Workshop”
Liverpool, UK
Invited Key Note Address: Drug-induced liver injury
53. 9/8/13 – American Chemical Society Fall Meeting
Indianapolis, IN
Invited Speaker: Biomarkers for the diagnosis and management of drug-induced liver injury
54. 9/4/13 – Abbvie Seminar
Waukegan, IL
Invited Speaker: Hepatotoxicity in Drug Development
55. 6/23/13 – National Center for Safety Evaluation of Drugs, National Institutes for Food and Drug Control
Beijing, China
Invited Speaker: Why Good Drugs are Sometimes Bad for the Liver

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56. 6/22/13 – 4th Sino-American Symposiums on Clinical and Translational Medicine: Better Communication for Better Outcomes in Translational Research Collaboration
Beijing, China
Co-Chair: Advanced Methodologies and Tools in Translational Research: Drug Induced Liver Injury (DILI) Issues
Invited Speaker: Building the Sino-US Collaborative Network on DILI: Pre and Post Market Drug Safety and Clinical Applications
57. 6/4/13 – 6/5/13 – World Pharma Congress
Philadelphia, PA
Key Note Address: Is Drug Safety Really a Problem in 2013?
Invited Speaker: Practical Applications of DILLsym™, a Mechanistic Model of Drug-induced Liver Injury
58. 5/18/13 – Third Annual Hepatology Live Conference - East Meets West – Collaborations and Partnerships in Hepatology & Navigating the Evidence Live
Athens, Greece
Invited Plenary Speaker: Drug Induced Cholestasis
Invited panelist in the drug induced liver injury patient case study workshops
59. 4/18/13 - 4/19/13 – New England Drug Metabolism Discussion Group and ISSX – Workshop: The Role of Drug Metabolism in Immune-Mediated Drug Toxicity: Molecular, Clinical and Mechanistic Aspects
Cambridge, MA
Invited Speaker: Genetic Determinants of IDILI – HLA Polymorphisms and Future Directions of Research
60. 3/10/13 – Annual FDA Hepatotoxicity Meeting: Detecting and Evaluating DILI
Hyattsville, MD
Invited Speaker: The Liver Safety Consortium
61. 3/8/13 – ASCPT Annual Meeting
Indianapolis, IN
Invited Speaker: Proteomics, Metabolomics and DILI Biomarkers
62. 2/27/13 – 2/28/13 – Innovative Medicines Initiative (IMI) Mechanism-Based Integrated Systems for the Prediction of Drug-Induced Liver Injury (MIP-DILI)
General Assembly Meeting
Amsterdam
Invited participant
63. 1/28/13 – 1/29/13 - Critical Path Institute Predictive Safety Testing Consortium FDA 2013 Annual Scientific Workshop
Silver Spring, MD
Invited participant in workshop
64. 1/23/13 - 1/25/13- Human Toxicology Project Consortium
Building Shared Experience to Advance Practical Application of Pathway-Based Toxicity: Liver Toxicity Mode-of-Action
Baltimore, MD
Invited speaker: Making Safer New Drugs without Animal Testing
Invited participant in workshop
65. 12/5/12 – Drug Information Association (DIA)

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DILI Biomarkers Webinar

Part 1: Drug Induced Liver Injury (DILI) In-depth Look into Causality and Biomarkers Puzzle

Part 2: Where Are We and Where Do We Need To Go?

Moderator and Invited Speaker

66. 11/9/12 - International Liver Safety Workshop: Liver Safety Assessment in Clinical Drug Development: Best Practices Workshop
Boston, MA
Co-Organizer and Moderator
67. 10/30/12 – Research Triangle Institute International
RTP, NC
Invited speaker: Why Good Drugs are Sometimes Bad for the Liver
68. 10/19/12 – Society of Toxicology Future Tox: Building the Road for 21st Century Toxicology and Risk Assessment Practices
Arlington, VA
Invited Speaker: Reducing Uncertainty through Virtual Organs
69. 9/16/12 – Sino-American Symposium on Clinical and Translational Medicine Satellite Workshop
Shanghai, China
Invited panelist with the Chinese SFDA, FDA and drug-induced liver injury experts to discuss developing a collaborative Chinese DILI network
70. 9/16/12 - Sino-American Symposium on Clinical and Translational Medicine Satellite Workshop
Shanghai, China
Invited Plenary Speaker: First Eight Years of the U.S. Drug-Induced Liver Injury Network
71. 9/15/12 – Sino-American Symposium on Clinical and Translational Medicine Satellite Workshop
Shanghai, China
Invited panelist with the Chinese SFDA, FDA and drug-induced liver injury experts to discuss DILI with the drug development and pre/post-market drug survey
72. 6/30/12 – 7th Shanghai Jiao Tong University Conference on Current Focus of Diabetes: New Technologies for Diabetes - from bench to bedside
Shanghai, China
Invited Speaker: The Problem of Hepatotoxicity in Diabetic Drug Development: The Legacy of Troglitazone
73. 6/28/12 – Sino-American Symposium on Clinical and Translational Medicine (SAS-CTM)
Shanghai, China
Invited Speaker: Drug Induced Liver Injury
74. 6/27/12 - Sino-American Symposium on Clinical and Translational Medicine (SAS-CTM)
Shanghai, China
Participant Round Table Discussion: Setting up translational medicine centers in China

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75. 6/21/12 - International Society for the Study of Xenobiotics (ISSX), European Annual Meeting
Grand Hotel Huister Duin
Netherlands
Invited Speaker: Using Inbred Mice to Identify Mechanisms Underlying Adverse Drug Events
Co-Chair: Symposium Adverse Drug Reactions: Focus on Mechanisms: Using Inbred Mice to Identify ADR Mechanisms
76. 6/9/12 – AASLD Clinical Research Single Topic Conference
Atlanta, GA
Course Director and Speaker: Acetaminophen Poisoning: Novel Biomarker Discovery in Healthy Volunteers and Patients with Acetaminophen Toxicity
Invited Speaker: Insights into the Management of Acetaminophen Poisoning from DILIsym- An In Silico Model of the Liver
77. 6/6/12 – World Pharma Congress Fourth Annual Tackling Drug-induced Idiosyncratic Hepatotoxicity
Philadelphia, PA
Keynote Speaker: Safety in Numbers: Exploring the Pre-Competitive Space
78. 4/3/12 – 4/4/12 – European Partnership for Alternative Approaches to Animal Testing (EPAA) Computational Chemistry Workshop, Revolutionizing Toxicology: Developing a research prospectus
Brussels, Belgium
Invited Participant in Workshop
79. 3/14/12 - FDA DILI Conference - Why DILI Idiosyncrasy? The Immune System and Beyond...Why do only a few people show serious liver dysfunction from drugs that nearly everybody else can tolerate or adapt to?
Silver Spring, MD
Invited Presenter/Moderator: How and why do people respond differently to the same drug?
80. 2/17/12 – 22nd Conference of the Asian Pacific Association for the Study of the Liver (APASL 2012)
Taipei, China
Invited Speaker: Recent advances in biomarkers for the diagnosis and management of drug-induced liver injury
81. 2/17/12 – 22nd Conference of the Asian Pacific Association for the Study of the Liver (APASL 2012)
Taipei, China
Invited Speaker: State of the Art Plenary Lecture: The US Drug Induced Liver Injury Network
82. 1/26/12 – National Institutes for Health
RTP, NC
Invited Speaker: Recent Advances in understanding Idiosyncratic Hepatotoxicity
83. 11/5/11 – AASLD The Annual Liver Meeting 2011
San Francisco, CA
Invited Speaker: Drug-induced Liver Injury

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Special Interest Group Program: The Role of Adaptive Immunity in DILI

84. 10/26/11 – FDA/CDER Seminar Series
Silver Springs, MD
Invited Speaker: Why Good Drugs are Sometimes Bad for the Liver
85. 10/17/11 – Acute Liver Failure Study Group - Pathogenesis of Liver Injury Forum
Dallas, TX
Invited Speaker: GWAS Studies in DILIN
86. 10/4/11 - Tox 21 Symposium at the New York Academy of Sciences
New York, NY
Invited speaker: Idiosyncratic Hepatotoxicity: From Man to Mouse to Computer
87. 9/22/11 – Research Triangle Park Platform Technology and Science Discovery
Science Day
RTP, NC
Invited Plenary Speaker: Translation, Integration and Investigation: The Path to
Discovering Safer Medicines
88. 8/30/11 – 242nd American Chemical Society National Meeting
Denver, CO
Invited Speaker: Idiosyncratic Drug Induced Liver Injury: From Man to Mouse to
Computer
89. 8/16/11 – 27th International Conference on Pharmacoepidemiology & Therapeutic
Risk Management
Chicago, IL
Invited Speaker in Concurrent Symposium: Drug - Induced Liver Injury: Latest
Developments on Premarket Regulatory Guidance and Approaches to Postmarket
Surveillance
90. 6/8/11 – World Pharma Congress: New Assays and Tools for Predicting Hepatotoxicity
Philadelphia, PA
Invited Speaker: Mechanistic Insights into Hepatotoxicity
91. 5/15/11 – American Thoracic Society Annual Meeting
Denver, CO
Invited Speaker: Idiosyncratic Hepatotoxicity
92. 5/9/11 – AGA: Digestive Disease Week 2011
Chicago, IL
Invited State-of-the-Art Lecture: When Good Drugs are bad for the Liver
93. 4/13/11 – ASPET 2011 Annual Meeting, part of the Experimental Biology 2011
Annual Meeting
Session Title: Pharmacogenomics to Address Adverse Drug Events
Washington, DC
Invited Speaker: Understanding Idiosyncratic Drug-Induced Liver Injury
94. 3/23/11 – AASLD/FDA/PHRMA Meeting: hepatotoxicity Special Interest Group: Drug
Induced Liver Injury: Are we ready to Look?
Silver Spring, MD
Meeting Advisor and Session Speaker: Studies in Healthy Subjects Exposed to Drugs

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95. 3/7/11 – Defense Threat Reduction Agency, Chemical and Biological Technologies Directorate All Hands Meeting
Ft. Belvoir, VA
Invited Speaker: Importance of Drug Safety to Defense Threat Reduction
96. 2/27/11 – Liver Disease Day
Indian Wells, CA
Invited Speaker: Why good drugs can be bad for the liver
97. 12/16/10 – Liver Toxicity Biomarker Workshop at the FDA
Silver Spring, MD
Invited Speaker: Liver Toxicity Biomarkers: Current state of the field and novel areas of research
98. 11/9/10 - Mitigating Safety Risks in Early Clinical Development & Post-Approval Drug Development
Philadelphia, PA
Invited Speaker: Idiosyncratic Liver Injury: Challenges and Approaches
99. 11/8/10 – Mitigating Safety Risks in Early Clinical Development & Post-Approval Drug Development
Philadelphia, PA
Invited moderator of breakout discussion group: How to Minimize the Risk of Drug-Induced Liver Injury
100. 9/5/10 – International Society for the Study of Xenobiotics 9th International Meeting
Istanbul, Turkey
Invited Speaker: Understanding Idiosyncratic Hepatotoxicity: From Man to Mouse to Computer
101. 6/16/10 – World Pharmaceutical Congress Fourth Annual Monitoring Cardiotoxicity and Drug Safety
Philadelphia, PA
Invited member of expert panel: Casting the Right Safety Net: Exploring Creative Options for Predicting Drug Safety
Invited Plenary Talk: New approaches to understand idiosyncratic hepatotoxicity
102. 6/8/10 – Delaware Valley Drug Metabolism Discussion Group Rozman Symposium
Langhorne, PA
Invited Speaker: Why Good Drugs are Sometimes Bad for the Liver
103. 5/22/10 – 2010 Bio-X International Translational Medicine Symposium
Shanghai, China
Invited Speaker: Predicting and understanding drug-induced liver injury: an emerging role for personalized medicine
104. 5/15/10 - Tuberculosis Trials Consortium (TBTC) Semi-Annual Group Meeting
New Orleans, LA
Invited Speaker: TB and hepatotoxicity: A great opportunity for biomarker discovery
105. 4/26/10 – 2010 Economic Development Summit on Seizing Economic Opportunity through the Botanical Medicine and Integrative Health Industry

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Asheville, NC

Invited speaker: Safety of Natural Products: A Competitive Advantage for NC

106. 3/25/10 – Annual meeting of the American Association for the Study of Liver Diseases, Drug-Induced Liver Injury: Getting the Medicine and Science Together
Silver Spring, MD
Moderator of morning session IIIA: The Hamner Institute for DILI Research Programs
Invited speaker: Plans and Progress of The Hamner Programs
107. 3/16/10 – Serious Adverse Event Consortium Phenotyping Standardization Project
Consensus Conference
Hinnton, Cambridge, UK
Co-Chair: DILI Expert Working Group
108. 3/10/10 - Annual meeting of the Society of Toxicology
Salt Lake City, UT
Invited speaker: Novel Research Approaches and Animal Models in Translational Toxicology
109. 3/4/10 – Research Triangle Park Drug Metabolism Discussion Group - Winter Symposium
RTP, NC
Plenary talk: Impact of Drug Metabolism Science in the 21st Century
110. 2/26/10 – FDA Institute of Medicine, Forum on Drug Discovery, Development and Translation
Washington, DC
Invited talk: The Hamner-UNC Institute for Drug Safety Sciences
111. 6/30/09 – Center for Drug Safety Sciences Inaugural Symposium
Liverpool, UK
Invited talk: Biomarkers for Drug Induced Liver Injury
112. 6/23/09 – Drug Information Association Annual Meeting
San Diego, CA
Invited talk: The Institute of Medicine report of biomarkers for drug safety
113. 5/31/09 – American Gastroenterology Association Annual meeting
Chicago, IL
Invited speaker at annual course: Drug Induced Liver Injury
114. 4/8/09 – FDA/Pharma/AASLD Hepatotoxicity Symposium
Silver Spring, MD
Invited talk: Update on the IOM and DILIN research agendas
Session Chairman
115. 3/20/09 – American Society for Clinical Pharmacology and Therapeutics
Washington, DC
Invited Talk: Translational research approaches to improve drug safety
116. 1/25/09 – Molecular Medicine Tri-Conference
San Francisco, CA
Invited Talk: Novel preclinical approaches to predict drug induced liver injury

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Session Chairman

117. 1/16/09 – National Center for Toxicologic Research
Little Rock, AR
Invited talk: Novel approaches to study acetaminophen toxicity
118. 12/9/08 – New York Academy of Sciences symposium on Drug Safety
New York, NY
Invited talk: Novel approaches to understanding drug induced liver injury
119. 12/1/08 – NIH Conference on Nomenclature in Drug Induced Liver Injury
Bethesda, MD
Invited talk: Development of biomarkers for liver safety
Chair of afternoon session
120. 11/6-11/7/08 – CBI Symposium on Hepatotoxicity
Philadelphia, PA
Co-chair of Conference
Invited Speaker: Use of clinical trials to identify novel biomarkers of hepatotoxicity
121. 11/1/08 - Annual meeting of the American Association for the Study of Liver Diseases
San Francisco, CA
Breakfast workshop: Drug Induced Liver Disease
122. 10/28/08 – HESI Case Studies Workshop: Genomics Applications in Safety Studies
- Case Study Workshop
Washington, DC
Invited talk: Use on genomics to identify hepatotoxicity biomarkers in clinical trials: A case study in acetaminophen treated health volunteers
123. 10/24/08 – Institute of Medicine Workshop on Biomarkers for Drug Safety
Washington, DC
Invited Presentation: Hepatotoxicity Biomarker White Paper
Co-chair, Hepatotoxicity Biomarkers Discussion Session
124. 6/5/08 – Gordon Conference on Adverse Drug Reactions
Chairman of session entitled, Drug-Induced Liver Injury
Invited speaker: Approaches to study Drug-Induced Liver Injury in humans
125. 3/26-3/27/08 - FDA/Pharma/AASLD workshop: Detecting and Investigating Drug-Induced Liver Injury during Clinical Trials
Silver Spring, MD
Moderator: Session morning session entitled, “When to stop treatment with an investigational drug”
126. 6/6/07 – New England Drug Metabolism Discussion Group
Boston, MA
Dinner Speaker: Hepatotoxicity: Why preclinical models fail
127. 12/11/06 – NIGMS workshop: Understanding the genetic basis of medication safety
Bethesda, MD
Invited speaker – Idiosyncratic drug induced liver injury

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128. 8/15/06 – NIH Roadmap meeting on Predictive Models for Drug Safety Assessment
NIH Campus, Lister Auditorium
Key Note Address: Idiosyncratic hepatotoxicity: Why current animal preclinical models fail?
129. 12/01/05 - NIEHS Extramural Administrators Workshop
Wilmington, NC
Key Note Address: Human Experimentation in Environmental Health Research
130. 10/31/05 – 11/1/05 – NIEHS Center Directors Meeting
Vanderbilt, TN
Member Panel Discussion: P30 Clinical Research in Environmental Health Sciences
131. 9/29/05 – 9/30/05 - IBC Conference on Signal Detection and Risk Assessment
Washington, DC
Invited Speaker: Update on the Drug Induced Liver Injury Network (DILIN)
132. 9/16 – 9/18/05 –Single Topic Conference on Drug Induced Liver Injury sponsored by the American Association for the Study of Liver Diseases
Atlanta, GA
Co-Chair of Conference, also:
Invited speaker: Mechanisms underlying adaptation to Drug-Induced Liver Injury
133. 8/24/05 – The International Society for Pharmacoepidemiology
Nashville TN
Invited speaker
Topic: The Drug Induced Liver Injury Network (DILIN)
134. 6/5/05 – Gordon Conference on Adverse Drug Reactions
Chairperson of session entitled Drug-Induced Liver Injury
Invited speaker: Approaches to study Drug-Induced Liver Injury in humans
135. 4/28/05 –Annual Clinical Research Meetings
Washington DC
“State of the Art” Plenary Lecture
Topic: Drug Induced Liver Injury – Breaking the promise of genomics to drug Development
136. 11/9/04 – Sixth International Workshop on the Pharmacodynamics of Anti-Cancer Agents
Venice, Italy
Invited talk: Metabolism in the Gut
137. 11/1/04 – Annual meeting of The American Association for the Study of Liver Diseases
Boston MA
The Hyman Zimmerman State-of-the-Art Lecture
Topic: Hepatocellular injury caused by drugs and what’s being done about it
138. 11/1/04 - Annual Meeting of the American Association for the Study of Liver Diseases
Boston, MA
Symposium entitled CYPs and liver diseases
Invited Talk – CYPs and Drug Induced Liver Injury

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139. 10/31/04 - Annual Meeting of the American Association for the Study of Liver Diseases
Boston, MA
Breakfast workshop: Mechanisms of Drug Induced Liver Disease
140. 10/30/04 - Annual Meeting of the American Association for the Study of Liver Diseases
Boston, MA
Meet the Professor Luncheon: Drug induced transaminitis
141. 8/30/04 - International Society for the Study of Xenobiotics Meeting
Vancouver, British Columbia
Invited talk: CYP3A4 and P-gp in the disposition of drugs: Clinical studies
142. 6/21/04 - 2004 Pharmacogenomics Conference
Nashville TN
Invited Talk: Genomic Approaches to Understanding Drug Induced Liver Disease
143. 6/14/04 – Annual meeting of The Society of Toxicologic Pathology
Salt Lake City, UT
Key Note Address: Drug Induced Liver Disease – A Clinician’s Perspective
144. 10/26/03 - Annual Meeting of the American Association for the Study of Liver Diseases
Boston, MA
Meet the Professor Luncheon: Mechanisms of Drug Induced Liver Disease
145. 10/25/03 - Annual Meeting of the American Association for the Study of Liver Diseases
Boston, MA
Co-moderator: Symposium on Toxicity and Drug Metabolism
146. 10/25/03 - Annual Meeting of the American Association for the Study of Liver Diseases - Post Graduate Course
Boston, MA
Meet the Professor Luncheon: Drug Induced Liver Disease: Rezulin, Duract, Trovan and others
147. 10/13/03 – Clinical Investigation Student Training Forum
National Institutes of Health – 50th Anniversary celebration of the Clinical Center
Invited talk and round table discussion: How to be a successful academician
148. 7/14/03 – International Food Technology meeting
Chicago, IL
Invited talk: The Role of Furocomarins in Grapefruit juice: drug Interactions
149. 7/13/03 – Drug Metabolism Gordon Conference
Holderness, NH
Discussion Leader: Clinical Aspects of Hepatotoxicity
Invited Speaker: Acute hepatocellular injury due to drugs
150. 5/6/03 – Tools for Pre-Approval Drug Safety
Rockville, MD
FDA course for medical reviewers

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- Invited talk: Hepatotoxicity and Drug Safety Evaluation
151. 2/28/03 – Symposium on Drug Induced Liver Disease
Washington, DC
Invited Talk: Clinical Research Methods for Identification of Susceptibility Factors for Drug Induced Liver Disease
 152. 2/23-24/03 – Co-Chair Symposium on Drug Induced Liver Disease
Washington, DC
Invited Talk: Pharmacogenomic Approaches
 153. 11/2/02 – Annual Meeting, American Association for the Study of Liver Diseases
Boston, MA
Meet the Professor Breakfast: Mechanisms of Drug Induced Liver Injury
 154. 11/2/02 - Annual Meeting - American Association for the Study of Liver Diseases
Boston, MA
Meet the Professor Luncheon: Pharmacogenetics and Drug Induced Liver Injury
 155. 7/22/02 – American Society of Pharmacology and Therapeutics
Washington, DC
Invited Talk: Citrus juice / drug interactions
 156. 5/30/02 – Centers for Education and Research in Therapeutics Annual Meeting
Chapel Hill, NC
Invited Talk: Pharmacogenomics and Adverse Events
 157. 2/06/02 – Toxicology Forum
Washington, DC
Invited talk: Mechanism-based inactivation by fruit juices
 158. 10/10/01 – International Society for the study of Xenobiotics
Munich, Germany
Invited Talk: Role of Transporters in Oral Availability
 159. 9/17/01 The Benzon Symposium No.48
Drug Metabolism: Regulation and Importance
Copenhagen, Denmark
Invited Talk: Probe based tests of CYP3A enzymes
 160. 7/10/01 – Toxicology Forum
Aspen, CO
Invited talk: Mechanism of Drug Induced Liver Disease
 161. 3/7/01 – American Society for Clinical Pharmacology and Therapeutics
Orlando, FL
Invited talk: Drug Interactions with Herbal Products and Foods
 162. 2/13/01 – FDA/Pharma Symposium on Drug Induced Liver Injury
Rockville, MD
Invited Talk: Pharmacogenetic/Pharmacogenomic approaches
 163. 11/14/00 – European Society for Clinical Pharmacology
Basel, Switzerland

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Invited Talk: Diet/Drug Interactions

164. 11/3/00 Annual Meeting of the American Association for the Study of Liver Diseases
Boston, MA
Meet the Professor Luncheon: Pharmacogenetics and Drug Induced Liver Injury
165. 10/28/00 Annual Meeting of the American Association for the Study of Liver Diseases
Dallas, TX
Meet the Professor Breakfast: Update on Drug Induced Liver Disease
166. 10/17/00 Drug Information Agency's Symposium on Biomarkers
Arlington, VA
Invited talk: Use of Biomarkers in Assessing Drug-induced Liver Disease in Clinical Trials
167. 7/16/00 International Microsomes and Drug Oxidations Symposium
Stresa, Italy
Chairman, Session entitled, Extrahepatic Metabolism
168. 6/19/00 IV International Symposium on Drug Interactions
Baltimore, MD
Invited talk: Citrus juices and transporters in the small bowel
169. 6/12/00 International Society for the Study of Xenobiotics
Drug Metabolism Workshop
Dundee, Scotland
Invited talk: Role of transporters in drug disposition
170. 4/17/00 Millennium World Congress on Pharmaceutical Sciences
San Francisco, CA
Invited Talk: Clinical aspects of drug transporters
132. 11/13/99 International Society for the Study of Xenobiotics Annual Meeting
Nashville, TN
Invited Talk: Extrahepatic drug metabolism
133. 11/7/99 Annual Meeting of the American Association for the Study of Liver Diseases
Dallas, TX
Meet the Professor Breakfast: Update on Drug Induced Liver Disease
134. 9/13/99 Barnett International Symposium on Drug-Drug Interaction
Washington, DC
Chairperson of entire meeting
Invited Talk Use of the Erythromycin Breath test in Predicting CYP3A4 Drug Interactions
135. 8/10/99 International Symposium, Membrane Transporters: New Perspectives in Drug Delivery and Drug Targeting,
Ascona, Switzerland
Plenary talk: The basis and consequences of variable MDR1 expression

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136. 11/8/98 American College of Clinical Pharmacy Annual Meeting
Cincinnati, OH
Therapeutic Frontiers Award and Plenary Lecture
The role CYP3A4 and P-glycoprotein in controlling systemic availability of orally administered drugs
137. 10/12/98 - Symposium on Drug Induced Liver Disease; Co-chairman
Chicago, IL
Invited Talk: Role of bioactivation enzymes
138. 10/7/98 - Esteve foundation Symposium VIII: Variability in human drug response
Sitges, Spain
Invited Talk: Transporters: Pharmacokinetic/pharmacodynamic/therapeutic and toxicological impact
139. 9/18/98 - International Congress of Clinical Applications of Breath Tests in Gastroenterology and Hepatology
Rome, Italy
Invited Talk: The erythromycin breath test
140. 7/22/98 12th International Symposium on Microsomes and Drug Oxidations
Montpellier, France
Invited Plenary Session Talk: Extrahepatic Distribution and Role of CYP3A Enzymes
141. 3/1/98 - American Academy of Dermatology Annual Meeting
Orlando, FL
Invited talk: The role of cytochromes P450 in drug interactions
142. 1/20/98 - American Association of Pharmaceutical Scientists Frontier Symposium
Bethesda, MD
Invited talk: Clinical Aspects of Cytochrome P450 Induction
143. 12/15/97 - International Business Conference on Drug Interactions
Washington, DC
Invited Talk: Use of probe substrates in clinical trials
144. 11/7/97 American Association for the Study of Liver Diseases Annual Meeting
Chicago, IL
Postgraduate Course Liver Injury Update: Clinical implications of mechanistic role of cells of the liver
Invited presentation: The cytochromes P450: implications in prevention and treatment of drug-induced liver disease
145. 7/13/97 - International Business Conference on Drug Interactions
London, England
Invited Talk: Understanding drug interactions involving CYP3A4
146. 7/9/97 - Gordon Conference on Drug Metabolism
Plymouth, NH
Implications of noninvasive tests of CYP3A4
147. 7/7/97 - Gordon Conference on Drug Metabolism
Plymouth, NH
Discussion Leader, Session on Clinical Relevance of Drug Interactions

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- Invited talk: Clinical Relevance of Drug Interactions Involving CYP3A4
148. 7/17/97 - International Business Conference - Drug-Drug interaction
London, England
Invited Talk: Understanding Drug Interactions Involving CYP3A4
 149. 5/16/97 - The Impact of Pharmacokinetics in Modern Drug Development
San Francisco, CA
Invited talk: A Human study supporting the role of intestinal p-glycoprotein in limiting the oral availability of drugs
 150. 4/10/97 - Food and Drug Administration
Silver Spring, MD
Invited Talk: The Emerging Role of CYP3A4 and P-glycoprotein in determining drug bioavailability
 151. 4/7/97 - Third Annual International Business Conference on Pharmacogenetics
Washington, DC
Program Chairman
Invited talk: CYP3A4, P-glycoprotein, and oral availability of drugs
 152. 3/9/97 - American Society for Clinical Pharmacology and Therapeutics Annual Meeting
San Diego, CA
Symposium: The intestinal barrier
Topic: The role of CYP3A4 in limiting the oral availability of drugs
 153. 12/10/96 - International Business Conference on Drug Interactions
Bethesda, MD
Topic: The mechanistic basis for the grapefruit juice effect
 154. 10/23/96 - International Society for the Study of Xenobiotics
San Diego, CA
Symposium: Enzyme Induction
Topic: The effects of diet and medications on regulation of CYP3A4 and MDR1 in human intestine
 155. 8/9/96 - Fifth International Congress on Clinical Pharmacology
Buenos Aires, Argentina
Symposium: Drug interactions involving CYP3A4 and CYP1A2
Topic: Understanding drug interactions involving CYP3A4
 156. 7/30/96 - Eighth Japanese American Forum of Drug Metabolism
Seattle, WA
Symposia: Optimum delivery of biologic and xenobiotic drugs
Topic: MDR1 transport protein and P450 enzymes as barriers to oral drug availability
 157. 5/27/96 - International Business Conference on Pharmacogenetics
Washington, DC
Topic: Use of the erythromycin breath test in drug development
 158. 4/26/96 - American College of Physicians Annual Meeting
San Francisco, CA

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- Symposium: Drug Induced Liver Disease
Topic: The role of cytochromes P450 in drug induced liver disease
159. 11/20/95 American Association of Pharmaceutical Scientists
San Diego, CA
Invited talk: Use of ketoconazole to inhibit taxol metabolism in patients
160. 11/13/95 First International Symposium on Drug interactions
St. Louis, MO
Plenary "State of the Art" Lecture
Topic: The clinical significance of drug interactions
161. 9/5/95 10th International Symposium on Therapeutic Drug Monitoring
Vienna, Austria
Symposium: Use of Liver Function Tests in Transplantation
Topic: The use of the erythromycin breath test in transplantation
162. 7/11/95 Annual United Kingdom Drug Metabolism Group Meeting
Nottingham, England
Plenary Talk: Noninvasive probes of CYP3A enzymes: Problems and Prospects
163. 4/15/95 American Society for Experimental Therapeutics Annual Meeting
Atlanta, GA
Symposium: Validation and application of noninvasive probes of human CYP3A
Topic: Clinical Applications of the erythromycin breath test
164. 3/7/95 Society of Toxicology Annual Meeting
Baltimore, MD
Symposium: The toxicological implications of microsomal induction in the
development of novel compounds
Topic: Implication of induction of CYP1A2 and CYP3A4 in drug interactions and
susceptibility to environmental disease
165. 2/13/95 Drug Information Association
Toronto, Canada
Symposium: Understanding drug interactions
Topic: The role of P4503A4 in drug interactions
166. 11/14/94 American Association for the Study of Liver Diseases
Chicago, IL
Early Morning Workshop, Co-Chairman
Topic: Drug Induced Liver Disease
167. 7/20/94 International Meeting on Microsomes and Drug Oxidations
Toronto, Canada
Topic: CYP3A enzymes in human intestine
168. 7/8/94 14th European Workshop on Drug Metabolism
Paris, France
Topic: Intestinal Metabolism
169. 5/23/94 FDA Symposium
Washington, DC
Topic: Women in Clinical Trials

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170. 1/25/93 Institute of Medicine Forum on Drug Development
Washington, DC
Workshop entitled, Enzymes of Drug Metabolism: Importance to Drug Safety and Efficacy
Topic: Metabolism in the Gut
171. 11/16/92 Association of American Pharmaceutical Scientists Annual Meeting
San Antonio, TX
PPDM/MNPC Joint Symposium: In vitro/In Vivo Correlation in Hepatic P450-Mediated Drug Metabolism
Topic: Clinical Significance of Inter-patient Differences in Cytochrome P450III A Activity
172. 11/2/92 International Society for the Study of Xenobiotics - Annual Meeting
Short Course
Miami, FL
Topic: In Vivo Studies of Human P450s - Effect on Pharmacokinetic
173. 10/31/92 American Association for the Study of Liver Diseases Annual Meeting
Research Workshop
Chicago, IL
Topic: Noninvasive Measurements of Human Cytochromes
174. 7/14/92 Gordon Conference on Drug Metabolism
Plymouth, NH
Discussant: Session Entitled, Noninvasive Tests of P450s in Patients
175. 7/14/92 Gordon Conference on Drug Metabolism
Plenary Session
Plymouth, NH
Topic: First Pass Metabolism of Drugs by P450III A in Gut
176. 11/5/90 American Association of Pharmaceutical Scientists Annual Meeting
Research Symposium
Las Vegas, NV
Topic: The Erythromycin Breath Test
177. 6/25/90 VIIIth International Symposium on Microsomes and Drug Oxidations
Research Symposium
Stockholm, Sweden
Topic: *In Vivo / In Vitro* Characterization of Cytochrome P450III A; Implications for the Use of Cyclosporine and Calcium Channel Blockers
178. 7/9/89 Gordon Conference on Pharmacology and Toxicology
Plenary Session
Plymouth, NH
Topic: Noninvasive Assays of Cytochromes P-450 in Rats and patients
179. 10/11/88 American Society of Pharmacology and Experimental Therapeutics
Research Plenary
Montreal, Canada
Topic: The Nitrosodimethyl Amine Breath Test

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180. 10/27/87 American Association for the Study of Liver Diseases
Plenary Session
Chicago, IL
Topic: Erythromycin Breath Test
181. 8/20/85 American Society for Pharmacology and Experimental Therapeutics
Research Symposium, Annual Meeting
Boston, MA
Topic: Human Liver Cytochromes P-450
182. 5/19/85 American Gastroenterology Association
Research Plenary, American Association for the Study of Liver Disease,
New York, NY
Topic: Identification of a Dexamethasone Inducible Isozyme of Cytochrome P-450 in
Rat and Human Intestine
183. 4/6/82 The American Society for Microbiology
Plenary Session, Annual Meeting
New York, NY
Topic: Paralysis in a Drug Addict

Abstracts – Available on request

TEACHING ACTIVITIES:

Invited talks and Courses Taught:

University of California San Francisco
Spring 2018 PSPG/CERSI Seminar Series, Invited Speaker
San Francisco, CA
Topic: Using Quantitative Systems Toxicology to Improve Drug Safety
4/10/18

University of North Carolina at Chapel Hill
Drug Metabolism Module graduate course (DPMP 890) – Dr. Philip C. Smith
Chapel Hill, NC
Topic: Drug Induced Liver Injury, DILI
3/7/2018

University of North Carolina at Chapel Hill
Advanced Toxicology Course (TOXC_707) – Dr. James A. Swenberg
Chapel Hill, NC
Topic: Idiosyncratic Hepatotoxicity
2/21/18

AASLD – The Liver Meeting 2017: Hepatotoxicity Special Interest Group
Symposium at the 2017 Liver meeting
Co-moderator: Controversial Issues – Clinical Cases, Monitoring, and
Regulatory Issues, Postgraduate Education Course
Washington, DC
10/20/17

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University of North Carolina at Chapel Hill
Advanced Toxicology Course (TOXC_707) – Dr. James A. Swenberg
Chapel Hill, NC
2/22/17
Topic: Human Toxicology: Drug-induced Liver Injury

Weill Cornell Medical College 2016/2017 Marcus Reidenberg Lecture
Department of Pharmacology
New York, NY
Topic: “Why good drugs are sometimes bad for the liver”
1/17/17

AASLD - The Liver Meeting 2016: Hepatotoxicity Special Interest Group:
Improving Causality Assessment in Drug Induced Liver Injury Continuing Medical
Postgraduate Education Course
Session Moderator
Boston, MA
11/11/16

Society of Toxicologic Pathology Modular Course: Toxicologic Pathology of the
Hepatobiliary System
Invited speaker: Assessment of drug induced liver injury in clinical trials
Raleigh, NC
10/26/16

Society of Toxicology 2016 Annual Meeting
Co-chair of Continuing Education Course: Approaches to Investigate and
assess risks associated with idiosyncratic drug-induced liver injury
New Orleans, LA
Lecture: Clinical Perspective including Risk Identification and Management
3/13/16

University of North Carolina at Chapel Hill
Advanced Toxicology Course (TOXC_707) – Dr. James A. Swenberg
Chapel Hill, NC
3/07/16
Topic: Human Toxicology: Drug-induced Liver Injury

Washington State University Allen I. White Lecture
School of Pharmacy
Spokane, WA
Invited lecturer: “Why good drugs are sometimes bad for the liver”
3/2/16

Weill Cornell Medical College
Department of Pharmacology
New York, NY
Topic: “Why good drugs are sometimes bad for the liver”
1/19/16

University of North Carolina at Chapel Hill
Center for Pharmacogenomics and Individual Therapy
UNC Eshelman School of Pharmacy

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Chapel Hill, NC
Invited Speaker: "Why Good Drugs are sometimes bad for the Liver"
11/10/15

University of North Carolina at Chapel Hill
Drug Metabolism Course (MOPH 810) – Dr. Dhiren Thakker
Chapel Hill, NC
Topic: Drug-induced Liver Injury (DILI)
10/9/2015

University of North Carolina at Chapel Hill
T32 Training Forum
Chapel Hill, NC
Invited Speaker: Drug Safety Sciences
5/11/15

NIH – AASLD Workshop
Liver Injury from Herbal and Dietary Supplements
Topic: Herbal and Dietary Supplement (HDS) Use in the United States
Role: Moderator
Bethesda, MD
5/4 – 5/5/2015

University of North Carolina at Chapel Hill
Advanced Toxicology Course (TOXC_707) – Dr. James A. Swenberg
Chapel Hill, NC
3/16/15
Topic: Human Toxicology: Drug-induced Liver Injury

University of Pennsylvania
GI Ground Rounds
Topic: DILI – From clinic to cage to computer
Center for Clinical Epidemiology and Biostatistics Research Seminar
Topic: Why Good Drugs are Sometimes bad for the Liver
Philadelphia, PA
2/28 – 2/19/2015

University of North Carolina at Chapel Hill
UNC Graduate Seminar: Royster Society of Fellows
Chapel Hill, NC
11/6/14
Topic: Why good drugs are sometimes bad for the liver

University of North Carolina at Chapel Hill
Drug Metabolism Course (MOPH 810) – Dr. Dhiren Thakker
Chapel Hill, NC
10/23/14
Topic: Drug and Metabolite-Induced Hepatotoxicity

University of North Carolina at Chapel Hill
Advanced Toxicology Course (TOXC_707) – Dr. James A. Swenberg
Chapel Hill, NC
2/07/14

January 16, 2019

Topic: Human Toxicology: Drug-induced Liver Injury

University of North Carolina at Chapel Hill
Drug Metabolism Course (MOPH 810) – Dr. Dhiren Thakker
Chapel Hill, NC
10/24/13
Topic: Drug Metabolism Induced Liver Toxicity

University of Michigan
Internal Medicine Ground Rounds
Ann Arbor, MI
Topic: Why Good Drugs are Sometimes Bad for the Liver
5/10/13

Quintiles
Ground Rounds
Morrisville, NC
4/10/13

University of North Carolina at Chapel Hill
Advanced Toxicology Course
Chapel Hill, NC
2/1/13
Topic: Human Toxicology: Drug-induced Liver Injury Part 2

University of North Carolina at Chapel Hill
Advanced Toxicology Course
Chapel Hill, NC
1/30/13
Topic: Human Toxicology: Drug-induced Liver Injury Part 1

University of North Carolina at Chapel Hill
Pulmonary and Gastrointestinal Therapeutics Fall 2012 Course (PHCY 445)
GI Module
Chapel Hill, NC
Topic: Liver Anatomy, LFTs and Drug Induced Liver Disease
11/15/12

AASLD: The Liver Meeting 2012
AASLD Meet the Professor Luncheon
Role: Co-moderator
Title: Pharmacogenetics and Drug-induced Liver Injury
Boston, MA
11/10/12

AASLD: The Liver Meeting 2012
AASLD Postgraduate course
Invited Lecturer
Topic: Causes and Clinical Features of Drug-induced Liver Injury (DILI): State-of-the-Art
Boston, MA
11/9/12

University of North Carolina at Chapel Hill

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Theory and Practice of Evaluating Human Health Risks of Chemicals Course
(ENVR 742) – Dr. Ivan Rusyn
Chapel Hill, NC
11/5/12
Topic: Drug Development in 2012

University of North Carolina at Chapel Hill
Drug Metabolism Course – Dr. Dhiren Thakker
Chapel Hill, NC
11/1/12
Topic: Drug Metabolism Induced Liver Toxicity

University of Southern California
Keck School of Medicine Seminar
10/11/12
Topic: Understanding Drug Induced Liver Injury: From Man to Mouse to
Computer

University of North Carolina at Chapel Hill
Advanced Toxicology Course
Chapel Hill, NC
3/2/12
Topic: Human Toxicology: Drug-induced Liver Injury Part 2

University of North Carolina at Chapel Hill
Advanced Toxicology Course
Chapel Hill, NC
2/29/12
Topic: Human Toxicology: Drug-induced Liver Injury Part 1

University of North Carolina at Chapel Hill
Clinical Pharmacology Forum
Chapel Hill, NC
12/2/11
Topic: Drug Metabolism and DDI

University of North Carolina at Chapel Hill
Drug Metabolism Course MOPH810 Fall 2011
Chapel Hill, NC
10/25/11
Topic: Drug and Metabolite-Induced Hepatotoxicity

Duke University
Duke Integrated Toxicology and Environmental Health Program
Durham, NC
9/9/11
Topic: Idiosyncratic Hepatotoxicity

Duke Clinical Research Institute
Duke Clinical Research Institute's Research Conference
Durham, NC
5/31/11
Topic: When good drugs are bad for the Liver

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University of North Carolina
Advanced Toxicology Course
Chapel Hill, NC
2/23/11
Topic: Human Toxicology: Drug-induced Liver Injury Part 2

University of North Carolina
Advanced Toxicology Course
Chapel Hill, NC
2/21/11
Topic: Human Toxicology: Drug-induced Liver Injury Part 1

Duke University
Duke University Integrated Toxicology and Environmental Health Program
Durham, NC
1/28/11
Topic: Idiosyncratic Hepatotoxicity

University of North Carolina
GPEN 2010 (Globalization of Pharmaceutical Education Network) Course
Chapel Hill, NC
11/11/10
Topic: Drug-Induced Toxicity: A Major Factor in the Clinical Failure of Drug Candidates

University of North Carolina
Advanced Toxicology Course
Chapel Hill, NC
3/1/10
Topic: Human Toxicology: Drug-induced Liver Injury Part 2

University of North Carolina
Advanced Toxicology Course
Chapel Hill, NC
2/26/10
Topic: Human Toxicology: Drug-induced Liver Injury Part 1

University of North Carolina
Institute for Pharmacogenomics and Individualized Therapy
Chapel Hill, NC
1/12/10
Topic: Understanding hepatotoxicity: from man to mouse to computer

University of North Carolina
Department of Medicine Grand Rounds
Chapel Hill, NC
12/3/09
Topic: Why good drugs are sometimes bad for the liver

University of Chicago
The Goldberg Lecture
Chicago, IL
11/26/09

January 16, 2019

Topic: New approaches to understand drug-induced liver injury

NC State University

Raleigh, NC

9/15/09

Toxicology Seminar Series

Topic: New approaches toward biomarkers for drug safety

University of Texas South Western

GI Grand Rounds

Dallas, TX

5/11/06- 5/12/06

Topic: Drug Induced Liver Disease

Moi Referral Hospital

Eldoret, Kenya

Visiting Professor

7/12/05 – 8/7/05

Duke University Medical School

Visiting Professor

Medical Grand Rounds

Durham, NC

3/25/05

Topic: Why are good drugs sometimes bad for the liver?

Indiana University Medical School

Visiting Professor

Medical Grand Rounds

Indianapolis, IN

3/8 – 3/9/05

Topic: Why are good drugs sometimes bad for the liver?

University of Florida Medical School

Visiting Professor

Medical Grand Rounds

Gainesville, FL

1/19/ - 1/20/05

Topic: Why are good drugs sometimes bad for the liver?

University of Connecticut Medical School

Visiting Professor

Medical Grand Rounds

Storrs, CT

1/15-16/05

Topic: Why are good drugs sometimes bad for the liver?

University of Kentucky

Gastroenterology Symposium

Invited Speaker

Lexington, KY

12/3/04

Topic: Drug Induced Liver Disease

January 16, 2019

Washington University, St Louis
The Burton Shatz Visiting Professor
Medical Grand Rounds
St Louis, MO
6/30 – 6/31/04
Topic: Understanding Drug Induced Liver Disease

National Institutes of Environmental Health Sciences
Toxicology Seminar Series
RTP, NC
11/6/03
Topic: Food: drug interactions – Lessons for Grapefruit Juice

Harvard University – Brigham and Women's Hospital
Visiting Professor and presenter at GI Grand Rounds
Boston, MA
1/29/03
Topic: Understanding Idiosyncratic Drug Induced Liver Disease

Research Triangle Park Drug Metabolism Discussion Group
Inaugural Banquet Guest Speaker
RTP, NC
10/14/99
Topic: Citrus juices and intestinal barrier function in man: Not pulp fiction

Georgetown University
Visiting Professor
Department of Medicine Grand Rounds
Washington, DC
9/2- 9/3/98
Topic: Why good drugs are bad for some people

University of Florida
Visiting Professor
Department of Medicine
Gastroenterology Research Seminar
Gainesville, FL
2/16-2/17/98
Topic: The grapefruit juice effect

Tufts Medical School
Pfizer Visiting Professor in Clinical Pharmacology
Boston, MA
11/19 - 11/21/96

Indiana University Medical Center
Visiting Professor
Department of Medicine
Indianapolis, IN
10/19/96

Michigan Society of Toxicology
Invited Plenary Talk
Ann Arbor, MI

January 16, 2019

5/19/95

Topic: CYP3A4: Studies in rats and patients

University of Uppsala, Sweden

Visiting Professor

Department of Clinical Pharmacology

Uppsala, Sweden

5/16 -5/17/95

University of California San Francisco

Visiting Professor

Department of Pharmacy

San Francisco, CA

1/6/95

Topic: The intestinal barrier

University of Chicago

Visiting Professor

Department of Pharmacology

Chicago, IL

6/23/94

Topic: The clinical relevance of CYP3A enzymes

University of Cincinnati

Visiting Professor

Department of Environmental Toxicology

Cincinnati, OH

11/2 - 11/3/93

Topic: Clinical Significance of Intestinal CYP3A

Wayne State University

Visiting Professor

Institute of Chemical Toxicology

Detroit, MI

7/10/93

Topic: The intestine as a metabolic barrier

University of Colorado

Visiting Professor

Division of Clinical Toxicology

Boulder, CO

4/8 - 4/9/93

Topic: The Erythromycin Breath Test

Indiana University

Visiting Professor

Department of Medicine Grand Rounds

Indianapolis, IN

12/8 - 12/9/92

Topic: Clinical Applications of Molecular Pharmacology

University of Pittsburgh

Visiting Professor

January 16, 2019

Division of Clinical Pharmacology
Pittsburgh, PA
5/6-5/7/92
Topic: Clinical relevance of inter-patient differences in P450III A activity

Medical College of Virginia
Medical Grand Rounds
Richmond, VA
4/16/92
Topic: Why are good drugs bad for some people?

University of Michigan
Medical Grand Rounds
Ann Arbor, MI
3/23/92
Topic: Why are good drugs bad for some people?

Delaware Valley Drug Metabolism Group
Philadelphia, PA
5/30/91
Topic: Clinical uses of noninvasive assays of P450III A

Vanderbilt University
Pharmacology Seminar
Nashville, Tennessee
9/10/90
Topic: Noninvasive Assays of P450III A in Patients

The University of Alabama
Gastroenterology Seminar
Birmingham, AL
9/21/89
Topic: Drugs and the Liver

The University of Michigan Medical Center, Department of Medicine
Grand Rounds
Ann Arbor, MI
4/21/89
Topic: Drugs and the Liver, an Update

Medical College of Wisconsin
Research Seminar - Departments of Pharmacology and Biochemistry

Milwaukee, WI
3/7/89
Topic: P-450III cytochromes: From rats to patients

Maine Medical Center, Department of Psychiatry
Grand Rounds
Portland, ME
11/15/88
Topic: Drug Interactions: What a psychiatrist should know

Medical College of Virginia, Department of Medicine

January 16, 2019

Medical Grand Rounds
Richmond, VA
3/3/88
Topic: Understanding Idiosyncratic Drug Reactions

The University of Michigan Medical Center
Medicine Grand Rounds
Ann Arbor, MI
1/27/87
Topic: Drug Reactions and Interactions

T32 Training Grant Co-Director:

One of three co-directors of the NIH UNC-Duke Collaborative Clinical Pharmacology Postdoctoral Training Program (T32 grant).

Faculty Mentoring:

- 1). Merrie Mosedale, PhD, Research Assistant Professor, Assistant Director of UNC IDSS
- 2). Rachel J. Church, PhD, Research Assistant Professor, Director, UNC Biomarker Core

Doctoral Thesis Committees:

- | | |
|---------------------------------|--------------|
| 1). James John Beaudoin (chair) | 2015-present |
| 2). Izna Ali, PharmD | 2014-present |
| 2). Cen Guo | 2013–2018 |
| 3). Leah Norona | 2015-2017 |
| 4). Natalie Holman | 2012-2016 |
| 5). Kyunghee Yang | 2011-2014 |
| 6). Latoya Griffin | 2009-2012 |
| 7). Tracy Marion | 2008-2010 |
| 8). Alison Hege Harrill | 2006-2008 |
| 9). Matthew Troutman | 2002 |
| 10). Keith Hoffmaster | 2001 |
| 11). Yuan Zing | 1998 |
| 12). Ching Ling | 1996 |
| 13). Zinge Hsu | 1994 |

Mentor for Medical Students in Doris Duke Clinical Research Fellowship:

- | | |
|--------------------|--|
| 1). Sara Peterson | 2006-2007 (First Place DD competition) |
| 2). Sheela Agarwal | 2004-2005 |
| 3). Ray Givens | 2001-2003 (First Place DD competition) |

Mentor for Senior House Office Projects:

January 16, 2019

- | | |
|----------------------|---|
| 1). Howard Ro | 1996-1997 (Winner of 1997 Research Prize) |
| 2). Kenneth Lown | 1988-1989 |
| 3). Kevin Foley | 1988-1989 |
| 4). Laurie Winkleman | 1987-1988 |

Clinical Mentor for UNC Program in Translational Medicine:

- | | |
|--|-------------|
| 1). Leah Norona, Doctoral Candidate | 2015 - 2017 |
| 2). Natalie Holman, Doctoral Candidate | 2012 - 2016 |

Gastroenterology Fellows/Postdoctoral Students:

- | | |
|-----------------------------|--------------|
| 1). Christina Battista | 2015-present |
| 2). Kyunghee Yang | 2014-2015 |
| 3). Merrie Mosedale | 2012-2014 |
| 4). Rachel Church | 2012-2014 |
| 5). Jingtao Lu | 2012-2014 |
| 6). Jeff Woodhead | 2011-2013 |
| 7). Catherine Lisa Kurtz | 2010-2012 |
| 8). Daniel Gatti | 2010-2011 |
| 9). Brett Howell | 2010-2011 |
| 10). Kristina DeSmet | 2009-2011 |
| 11). Alison Harrill | 2009-2010 |
| 12). Mark Russo (K-12/K-23) | 2003-2007 |
| 13). Claire Dees (K23) | 2000-2007 |
| 14). Mary Paine | 1997-1999 |
| 15). Robert Fontana | 1993-1995 |
| 16). Vas Janardan | 1993-1996 |
| 17). Ken Lown | 1990-1993 |
| 18). Kim Turgeon | 1989-1991 |
| 19). Joseph Kolars | 1987-1990 |

Graduate Students:

- | | |
|----------------------|-----------|
| 1). Leah Norona | 2015-2017 |
| 2). Natalie Holman | 2012-2016 |
| 3). Kyunghee Yang | 2012-2014 |
| 4). Stephane Mouly | 1999-2001 |
| 5). Shefali Malhotra | 1998-2002 |
| 6). Maria Banach | 1997-1999 |
| 7). Laurie Fortlage | 1993-1994 |
| 8). Fang Che | 1991-1993 |

UNC Curriculum in Toxicology Training Grant Postdoctoral Committee:

- | | |
|------------------------------|-----------|
| 1. Rhiannon N. Hardwick, PhD | 2013-2014 |
|------------------------------|-----------|

Undergraduate Student Mentoring:

January 16, 2019

- 1). Emily Fawcett, BS, NC State University, 2017

Recent Visiting Scientists:

- 1). Jae-Yong Chung, MD, PhD, Associate Professor, Seoul National University College of Medicine, Seoul Korea, Studying organ toxicity biomarkers, 8/1/16 – 1/1/08
- 2). Clive Dilworth, PhD, Chief Scientific Officer, Cyprotex, 1/10/17
- 3). Paul Walker, PhD, Head of Toxicology, Cyprotex, 1/10/17
- 4). James L. Stevens, PhD, Distinguished Fellow, Lilly Research, 1/13/17
- 4). Jerry Heneghan, MBA, Director of the Center for Innovation in Pharmacy Simulations, UNC School of Pharmacy, 2/10/17
- 5). Renee J. Brady, Postdoctoral Candidate, NC State, 2/23/17
- 6). Amy Rosenberg, MD, Director, Div of Biologics Research and Review, FDA, 3/20/17
- 7). Guncha Taneja, Postdoctoral Candidate, U of Houston, 4/10/17
- 8). Zack Kenz, PhD, Postdoctoral Candidate, MIT, 6/26/17
- 9). Alison Harrill, PhD, Geneticist, Biomolecular Screening Branch, NIEHS, 8/8/17
- 10). Ayako Suzuki, MD, PhD, Associate Professor at Duke, 8/14/17
- 11). Vinal V. Lakhani, PhD, Postdoctoral Candidate, Battelle Center for Math Medicine, 9/6/17
- 12). Alastair Mak, PhD, Postdoctoral Fellow, U of Toronto, 9/25/17
- 13). Yeshi Gebremichael, PhD, Research Scientist, University of Georgia, 10/6/17
- 14). Jia-bo Wang, Ph.D., Vice Director, China Military Institute of Chinese Medicine Integrative Medical Center for Liver Diseases, 1/25/18
- 14). Magnus Ingelman-Sundberg, PhD, Professor, Section head, Vice Chairman, Karolinska Institutet, 1/27/18 – 1/30/18

GRANT SUPPORT:

Current grant support:

NIH -UO1 DK065201
Title: "Drug Induced Liver Injury Network"
PI: Paul B. Watkins
Project period: 9/1/13 – 8/31/2018
Total direct cost: \$1,250,000
Effort: 20%

NIH/NIGMS, 2T32GM086330-06
Title: "UNC-Duke Collaborative Clinical Pharmacology Postdoctoral Training Program"
PI: Benjamin, Brouwer and Watkins (Multiple PIs)
Project Period: 7/1/11 – 6/30/2021

1 R44 GM123796-01
Subaward SciKon Innovation
PI: Mosedale
Project Period: 9/17 - 2/19
Standardization of a fluidic in vitro exposure system for IVIVE predictive toxicity data

January 16, 2019

This goal of this effort is to optimize methods and develop an SOP for an in vitro assay to predict drug-induced liver injury using the SciFlow1000 fluidic cell culture system.

Research Services Agreement, Allecra Therapeutics GmbH

PI: Mosedale

Project Period: 7/17 - 12/17

Identification of stress response pathways initiated in primary human hepatocytes exposed to AAI101. The goal of this project is to evaluate stress response pathway activation in human hepatocytes exposed to AAI101.

Effort: 10%

Research Funding Agreement, Wapta, LLC

PI: Mosedale

Project Period: 4/17 - 3/18

Investigation of an HLA supertype approach to identify patients susceptible to idiosyncratic adverse drug reactions. The goal of this project is to develop an HLA supertype approach to identify patients susceptible to adverse drug reactions.

Effort: 10%

Past grant support:

Funded Research Agreement, Gilead Sciences, Inc.

Director: Watkins

Project Period: 10/16 - 9/17

*A research plan to identify mechanisms underlying liver injury due to idelalisib
The overall goal of this research effort is to identify mechanisms underlying human liver toxicity due to idelalisib that may inform risk management strategies and next in class lead candidate selection.*

Sponsored Research Agreement, Organovo, Inc.

Co-PIs: Watkins and Mosedale

Project period: 5/16 - 8/17

Development of an in vitro model for compound-induced hepatic fibrosis

NIH/National Center for Advancing Translational Sciences: 1UL1TR001111-01

Title: "North Carolina Translational & Clinical Sciences Institute (NC TraCS)"

PI: Marschall S. Runge

"Drugs, Devices and Diagnostics Development (4D) Strategic Initiative"

Co-Director: Paul B. Watkins

Project period: 9/26/13 – 4/30/2018

Effort: 5%

"Organ Toxicity Biomarker Core," subcontract with UNC CTSA grant (above)

Sub-award to UNC IDSS

Funding provided by NC TraCS pilot grant program

PI: Paul B Watkins

Project period: 9/26/13 – 4/30/2017

Effort: 5%

NIH – 1U54RR024383-01

Title: "UNC Clinical and Translational Award"

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PI: Paul B. Watkins
Project period: 6/1/08 – 5/31/13
Total Direct Costs: \$65M
Effort: 50%

NIH, 1RC1DK087510-01
Title: "Revolutionizing preclinical safety testing"
PI: Watkins and Threadgill, (Dual PIs)
Project period: 9/1/09 – 7/30/12
Direct costs: \$1M
Effort: 10%

NIH -UO1 DK065201
Title: "Drug Induced Liver Injury Network"
PI: Paul B. Watkins
Project period: 9/1/03 – 8/30/12
Total direct cost: \$1,250,000
Effort: 20%

NIH, R-37 Merit Award GM 38149 -22
Title: "Effect of furanocoumarins and drugs on CYP3A4"
P.I.: Paul B. Watkins
Project Period: 9/1/99-8/31/10 (no cost extension)
Total Direct Costs: \$3,676,000
Effort: 30%

Doris Duke Charitable Foundation
Title: "Fellowship in Clinical Research for Medical Students"
PI: Paul B. Watkins
Project Period: 7/1/05 – 6/30/12
Total direct costs: \$800,000
Effort: 5%

Gates Foundation
Title: "Mechanisms underlying liver and kidney toxicity of DB289"
PI: Richard Tidwell
Project period 12/1/09 – 11/30/11
Direct Costs: \$1.5 M
Effort: 10%

NIH-5-M01-RR00042-31
Title: "General Clinical Research Center"
P.I.: Eugene Orringer, M.D.
Project Period: 12/01/99 - 11/30/10
Total Direct Costs: \$41M
Effort: 40% (Salary Only)

NIH, RO1 Award GM 38149 -12
Title: "CYP 3A4 and CYP3A5 in human intestine"
PI: Paul B. Watkins
Project Period: 8/1/94-7/31/98
Annual Direct costs: \$191,000
Total Direct Costs: \$802,000

January 16, 2019

NIH, R32 DK09280-02
Title: "Human intestinal flavin monooxygenases"
PI: Paul B. Watkins, mentor for Vas Janardan
Project period 07/15/95 - 07/14/97
Total Direct Costs: \$ 33,000 (salary support for Dr. Janardan)

NIH, PO1 ES04238
Title: "Integrated Clinical and Basic Studies in Toxicology"
Project Director: Philip Guzelian, M.D.
Annual Direct Costs: \$650,000
Total Direct Costs: \$3,000,000
Total Project Period: 3/1/92 - 2/28/97

NIH, R22 ESU5770-01
Title: "Noninvasive assays of P450IIIA enzymes in man"
PI: Paul B. Watkins
Project Period: 9/1/91 - 9/1/93
Total Direct Costs: \$100,000 total; \$80,000 direct
Annual Direct Costs: \$ 40,000

Veterans Administration Career Development Awards
Research Associate 1/87-1/91 (\$ 350,000 total; \$ 260,000 direct)
Associate Investigator 7/84-7/86 (\$ 70,000)

NIH, RO1 Award GM38149-01,
Title: "The environmental and genetic factors regulating HLP"
PI: Paul B. Watkins
Project Period: 8/86-8/89
Total Direct costs: \$ 300,000 total; \$ 210,000 direct

A.D. Williams Award (7,500) 1/86

NIH, NRSA Award F32 GM19034-01
Title: "Intestinal p-gp: Midazolam vs cyclosporine disposition"
Fellow: Mary Paine, Ph.D.
Mentor: Paul B. Watkins
Total Direct Costs: \$79,312
Total project period: 8/1/97 - 7/31/2000
Effort: 0%

Fujisawa Healthcare System
Title: "Predicting tacrolimus bioavailability from hepatic and enteric P-450 catalytic activity"
Project Director: Paul B. Watkins
Total direct costs: \$96,000
Total project period: 7/1/98 - 7/1/99

NIH SBIR R43 - GM50067
Title: "13C-erythromycin breath test to determine drug dosages"
Project Director: David Wagner, Ph.D.
Total Direct Costs: \$513,132
Total project period: 7/1/96 - 1/1/99

P.I.: Paul Watkins, M.D.

January 16, 2019

Title: "Noninvasive Assays of P450III A Enzymes in Man"

Total Project Period: 3/1/92 - 3/1/97

Total Direct Costs: \$625,034

Annual Direct Costs: \$120,000

PROFESSIONAL SERVICE:

MEMBERSHIPS IN PROFESSIONAL SOCIETIES:

American Association for the Study of Liver Diseases – Fellow (AASLD)
American Association for the Advancement of Science (AAAS)
American College of Physicians (ACP)
American Federation for Medical Research (AFMR)
American Gastroenterological Association (AGA)
American Society for Clinical Investigation (ASCI)
American Society for Clinical Pharmacology and Therapeutics (ASCPT)
American Society for Pharmacology and Experimental Therapeutics (ASPET)
Association of American Physicians (AAP)
International Association for the Study of the Liver (IASL)
International Society for the Study of Xenobiotics (ISSX)
North Carolina Medical Society (NCMS)
Society of Toxicology (SOT) National and North Carolina Chapters

FDA ACTIVITIES:

Scientific Advisory Board - National Center for Toxicological Research, 2010 - 2014
FDA consultant for Cardiovascular Drugs Advisory Committee 9/10/04
FDA consultant for Nonprescription Drugs Advisory Committee 9/19-20, 2002
FDA consultant for *In Vivo* Drug Metabolism Working Group 1997-99
FDA consultant for Liver Disease Working Group 1997-99

SCIENTIFIC ACTIVITIES:

Editorial Boards:

Clinical Pharmacology and Therapeutics – 4/05 - present
Drug Metabolism and Disposition - 1/1/94 – 98, 2002 - present
Pharmacogenetics - 1996 - present
Hepatology - 1/1/91 – 7/01/02

Ad hoc reviewer:

The Journal of Biological Chemistry, Hepatology, Journal of Clinical Nutrition,
Journal of Clinical Investigation, Gastroenterology, Annals of Internal Medicine,
Biochemical Pharmacology, New England Journal of Medicine, Molecular
Pharmacology, British Journal of Clinical Pharmacology, Clinical Pharmacology
and Therapeutics

Study Sections:

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Abstract Selection Committees - American Gastroenterology Association and American Association for the Study of Liver Diseases. 10/96-present; Chair Hepatotoxicity Section 10/09 – present

Abstract Review Committee - American Association for the Study of Liver Disease (AASLD), Chair "Hepatotoxicity: Pathogenesis and Mechanisms; Drug Metabolism, Toxicity and Therapeutics" 4/10 – 1/14

Rapporteur (Chairman), Mid-cycle review of 5 year, 40 million Euro SAFE-T Initiative supported by the European Union through the Innovative Medicines Initiative. This is a private public partnership to develop novel biomarkers of drug-induced injury to the liver, kidney and blood vessels. 4/1/11 – 12/1/11

Finalist interview panel, 2006 NIH Director's Pioneer Awards. 8/16 – 8/18/06

GCRC "Special" site visit review team 4/13/01

National Institutes of Health, Toxicology I Study Section 10/92- 10/96

Ad hoc reviewer for GMA-2 Study section, National Institutes of Health - 6/91

INSTITUTIONAL ADMINISTRATIVE ACTIVITIES:

Member - Eshelman School of Pharmacy Accreditation Self-Study Subcommittee - 1/2018- present

Member – Eshelman School of Pharmacy Full Professors' Committee – 3/2016 - present

Member – Eshelman School of Pharmacy Conflict of Interest Committee 8/2015 - present

Chair, UNC School of Medicine task force for the Precision Medicine Initiative – 5/2015 – 2016

Member of the School of Medicine Computational Medicine Committee – a committee with the goal to formalize a vision for a Computational Medicine program at UNC 1/2015 - 2016

Co-Director of UNC Strategic Initiative: Drugs, Devices, and Diagnostics Development (4D) 8/13 – 2017

Member of the NC State Institute for Emerging Issues Business Committee on Regulatory Science 2013- 2016

Member of CTSA TraCS Steering Committee 2012- 2017

Member of RTI Translational and Clinical Steering Committee 2013- 2016

Director – UNC Translational and Clinical Sciences Institute 7/06 -7/08

UNC Research Compliance Task Force 11/05 – 2016

January 16, 2019

Dean's Translational Research Committee 2/05 – 2016

Advisory Committee – Center for Function Bowel Disease 6/04 – 2016

Department of Psychiatry Chairman Search Committee 9-01-04 – 6-01-05

Division of Pharmacotherapy Search Committee – 1/01/04 – 8/1/04

Director, Mentored Clinical Research Scholars Program (K-12), 7/02 - 2016

Chair, Dean's Committee for Five Year Review of Cystic Fibrosis Center, Director:
Richard Boucher, M.D. 1/03 – 5/03

School of Medicine HIPAA Compliance Steering Committee – 12/02 – 2016

Medical Student Research Advisory Committee 7/01 – 2016

Advisory Board for Building Interdisciplinary Research Careers in Women's Health
(BIRCWH – K-12) Program 8/99 - 2016

Chairperson, Investigational Drug Service Advisory Committee - 6/00 – 2016

Chair, Clinical Research Advisory Committee for Industry Research 1/00 – 7/02

Dean's Scientific Advisory Committee 8/99 – 2016

Clinical Research Advisory Committee 8/99 – 2016

Advisory Committee for Center for Clinical Investigation and Therapeutics 12/98 –
8/99

Search Committee for Associate Dean of Research 11/98 – 6/99

Howard Hughes New Initiatives committee 10/98 – 8/1/99

Dean's Advisory Council on Clinical Research 2/98 - 8/99

Internal Review Committee for the Department of Medicine 6/98 -10/98

Chairperson, Dean's Task force for Clinical Research 10/96 - 5/97

University of Michigan Toxicology Training Grant Committee 1995 – 99

Deans' Search Committee for the Chairman of Department of Epidemiology 1995 -
96

Chairman, Department of Medicine Finance Committee 1993

Advisory Boards:

Invited Member: Scientific Advisory Board for the IMI TransBioLine Consortium
January 2019

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Member, Organizing committee for the SOT Metabolic Syndrome and Environmental Exposures Meeting June 2014 - present

Member, International Advisory Board for the International Society for the Study of Xenobiotics annual meeting January 2014-present

Co-Director, The Drug, Diagnostic and Device Development Program – a joint collaboration between University of North Carolina and Research Triangle Institute 2013- 2017

Member, Scientific Advisory Committee, Annual Sino-American Symposium on Clinical and Translational Medicine Beijing, China 2013 – present

Member, Committee on Translational Imaging, Health and Environmental Sciences Institute (HESI), Washington, DC 2012 – present

Member, Scientific Advisory Board – Innovative Medicines Initiative Joint Undertaking (IMI JU): “Mechanism-Based Integrated Systems for the Prediction of Drug-Induced Liver Injury; MIP-DILI” 2012 – present

Member, Selection and Advisory Committee of the Burroughs Wellcome Fund’s “Innovation in Regulatory Science Awards” 2012 – present

Member, Metabolic Syndrome Working Group of the Scientific Liaison Coalition of the Society of Toxicology 2011 – present

Founding member, International Society for Translational Medicine - 2010 - present

Scientific Liaison Task Force, Society of Toxicology - 2010 – present

Advisory Committee – International Drug Induced Liver Injury Consortium – 11/09 - present

External Advisory Committee – Centre for Drug Safety Sciences, University of Liverpool, UK 7/09 – present

Chairperson, Genetics Committee – National Institutes of Diabetes, Digestive and Kidney Diseases Drug Induced Liver Injury Network (DILIN) 1/09 – present

Hamner Institute – Scientific Advisory Board 3/07 – 2016

Scientific Management Committee, International Severe Adverse Events Consortium 7/07 – present

FDA Clinical Pharmacology Advisory Committee, Ad Hoc member 10/06 – present

External Ad Board, Vanderbilt Center in Molecular Toxicology, 11/15/05 – 5/2015

Committee member - Action Plan for Liver Disease Research - National Institutes of Diabetes, Digestive and Kidney Diseases 2/04 – present

January 16, 2019

Chairman, Steering Committee – National Institutes of Diabetes, Digestive and Kidney Diseases Drug Induced Liver Injury Network (DILIN) 7/1/03- present

Chairman, Executive Committee – National Institutes of Diabetes, Digestive and Kidney Diseases Drug Induced Liver Injury Network (DILIN) 7/1/03- present

Steering Committee - National Institute of Environmental Health Sciences Environmental Polymorphism Study (EPS) 6/01/02 – present

FDA/Pharma Hepatotoxicity Steering Committee 1999 – present

Board of Directors, Chief Scientific Advisor, Metabolic Solutions, Inc., Nashua, NH 1994 - present

Member, Drug Information Association Program Committee for the development of the “Multi Organ Injury: Drug Induced (Heart, Kidney, Liver, Skin) Meeting” 2013 – 2014

Member, Organizing Committee for the SOT Future Tox II CCT Meeting: “*In Vitro* Data and *In Silico* Models for Predicting Toxicology” 2012- 2014

FDA Scientific Advisory Board of the National Center for Toxicological Research 2010 – 2014

North Carolina Institute for Rare, Orphan and Neglected Diseases (IRON) – Member of Steering Committee 2011- 3013

Chairman, Hepatotoxicity Special Interest Group, American Association for the Study of Liver Diseases 11/09 – 11/13

External Advisory Committee for the Clinical and Translational Science Institute at the University of Michigan 9/09 – 12/11

FDA Scientific Advisory Board Subcommittee on Pharmacovigilance 6/10 – 7/11

Chairman, Scientific Advisory Committee for the Virtual Liver Project of the Food and Drug Administration’s Critical Path Initiative 11/08 – 7/1/10

Chairman, FDA Scientific Advisory Committee for the Liver Toxicology Biomarker Study of the Food and Drug Administration’s Critical Path Initiative 12/05 – 7/10

External Advisory Committee – Research Center in Minority Institution (RCMI), University of San Juan Puerto Rico 6/03 – 6/10

GlaxoSmithKline Scientific Advisory Board 2000 – 2009

Faculty Advisory Committee, University of North Carolina’s Environmental Program 2000 – 2008

Member, NIH Director’s Pioneer Award Finalist Interviewer Panel 8/7-9, 2006

January 16, 2019

Steering Committee – United Arab Agencies, Saudi Public Health Monitoring and Assessment Claim Studies Project; \$19 million grant to Johns Hopkins School of Public Health 6/01/03 – 5/31/06

Invited participant - National Institutes of Environmental Health Sciences Environmental Genomics Workshop to Consider Future Directions of Genomic Research 6/28/05 - 6/29/05

Chair, Scientific Advisory Board, Avmax, Inc., San Francisco, CA 1995 – 2004

Invited participant, National Center for Research Resources Strategic Planning Forum “Choices and Challenges: Future Directions for the NCCR” 9/10/03 – 9/11/03

Steering Committee – National Institute of General Medical Sciences Pharmacogenomics Network 11/01/02 – 12/31/03

International Life Sciences Institute’s Task Force on Non-Clinical/Clinical Safety Correlations 1999-2002

Chair, Advisory Committee for the Research Triangle Park Drug Metabolism Discussion Group 9/00 – 8/01

Chair, General Clinical Research Center National Task Force on Industry Research 8/00 – 8/01

Smith Kline Beecham Research and Development Advisory Board 1999 -2000

Program Committee for International Society for the Study of Xenobiotics annual meeting in Indianapolis, Indiana 10/00

Abbott-Genset Scientific Advisory Board 1998 – 2000

Health Advisory Board, Ecology and Environment, Buffalo, NY 9/97 – 1/00

Roche/Tasmar Safety Advisory board 1998 – 1999

Advisory Committee for Johnson & Johnson's \$30,000,000 grant to the Dermatology Department 1992- 1999

Scientific Advisory Committee for International Society for the Study of Xenobiotics annual meeting in Nashville, Tennessee, 10/99

Chairperson, Scientific Advisory Committee for Symposium on Drug Induced Liver Disease, Chicago, IL. 10/12/98 - 10/14/98

Dean's Advisory Committee on Gene Therapy 1995 – 1996

Chair, Advisory Board for Multicenter Cognex Rechallenge Study 1994-1996

Board of Directors, The GCRC National Directors Association 1992-96

University of Michigan Cardiovascular Research Center Exec Committee 1991-96

National Resources Council/National Academy of Sciences Committee on Comparative Toxicity of Naturally Occurring Carcinogens 1993-95

January 16, 2019

Chairperson, GCRC Directors Annual National Meeting, Reston, VA. 12/94

Ad Hoc Advisory Committee, Bio-nutrition Initiative, National Institute of Health 1993-94

Advisory Board, Michigan Psychiatric Research Center 1992 – 94

PATENTS:

1. Patent Number: 5,856,189
Date of Patent: 1/5/99
Title: Cell Culture Model for Drug Bioavailability
2. Patent Number: 5,100,779
Date of Patent: 3/31/92
Title: Method for Determining Function of a Unique Cytochrome P-450 Activity