CURRICULUM VITAE

Paul Brent Watkins, M.D.
Howard Q. Ferguson Distinguished Professor
Professor of Pharmacy, DPET, Eshelman School of Pharmacy
Professor of Medicine and Public Health
Director, Institute for Drug Safety Sciences
University of North Carolina at Chapel Hill
July 2022

PERSONAL INFORMATION:

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Chapel Hill, North Carolina 27514

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

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 Institute for Drug Safety Sciences 9/1/08 - present
Professor of Medicine (School of Medicine) – 8/1/99 – present
Professor of Pharmacy - 8/1/99 – present
Verne S. Caviness Distinguished Professor of Medicine – 8/1/99 – 7/1/11
Professor 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

HONORS AND AWARDS:

2021 State of the Art Plenary Lecture: Annual meeting of the Asia Pacific Association for the Study of the Liver.

2019 AASLD “Best of the Liver Meeting 2019” Abstract Award

2019 Experimental Biology and Medicine (EBM) Outstanding Reviewer Award

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

2017 State of the Art Plenary Lecture at the annual meeting of the International Society of Pharmacometrics

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

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

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:

Experimental Biology and Medicine 6/18-present
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:

Expert Peer Reviewer: U.S. FDA Office of Women's Health Intramural Grant Program 2021.

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:

Director of the UNC School of Pharmacy Precision Dosing Initiative
2019 – present

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

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:

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

American Society for Clinical Pharmacology and Therapeutics, Member of the CPT: Pharmacometrics and Systems Pharmacology (PSP) Scientific Advisory Board – 8/30/2019 – present

Member, Scientific Advisory Board for the European Innovative Medicine Initiative's TransBioLine Consortium. *This is a European research effort aimed at identifying and validating new safety biomarkers*. January 2019 – present .

Chairman, Scientific Advisory Board for the DILI-sim Initiative 2017-present

Member, Organizing committee for the SOT Metabolic Syndrome and Environmental Exposures Meeting June 2014 - 2017

Member, International Advisory Board for the International Society for the Study of Xenobiotics annual meeting January 2014-15

Co-Director, The Drug, Diagnostic and Device Development Program – a 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 – 17

Chaiman: Genetics Committee for the Drug Induced Liver Injury Network, 2013 - present

Member, Committee on Translational Imaging, Health and Environmental Sciences Institute (HESI), Washington, DC 2012 – 17

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 -2018

Member, Selection and Advisory Committee of the Burroughs Wellcome Fund's "Innovation in Regulatory Science Awards" 2012 – 2018

Member, Metabolic Syndrome Working Group of the Scientific Liaison Coalition of the Society of Toxicology 2011 – 2017

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 – 2018

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

The Hamner Institute – Scientific Advisory Board 3/07 – 2016

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

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

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

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

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

Scientific Management Committee, International Severe Adverse Events Consortium 7/07 – 2016

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

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

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

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

Committee member - Action Plan for Liver Disease Research - National Institutes of Diabetes, Digestive and Kidney Diseases 2/04 – 2017

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 – 2009

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

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 NCRR" 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

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

BIBLIOGRAPHY:

Completed publications in scientific journals:

Peer-reviewed journals:

1. Fecho K, Thessen AE, Baranzini SE, Bizon C, Hadlock JJ, Huang S, Roper RT, Southall N, Ta C, **Watkins PB**, Williams MD, Xu H, Byrd W, Dančík V, Duby MP, Dumontier M, Glusman G, Harris NL, Hinderer EW, Hyde G, Johs A, Su AI, Qin G, Zhu Q. Progress toward a universal biomedical data translator; Biomedical Data Translator Consortium. Clin Transl Sci. 2022 May 25. Online ahead of print

2. Woodhead JL, Siler SQ, Howell BA, **Watkins PB**, Conway C. Comparing the Liver Safety Profiles of 4 Next-Generation CGRP Receptor Antagonists to the Hepatotoxic CGRP Inhibitor Telcagepant Using Quantitative Systems Toxicology Modeling. Toxicol Sci. 2022 Jun 28;188(1):108-116. PMID: 35556143

3. **Watkins PB** Quantitative Systems Toxicology and Drug Development: The DILIsym Experience. Methods Mol Biol. 2022;2486:181-196. PMID: 35437723

4. Avigan M, **Watkins PB.** John R. Senior, MD. Obituary. Hepatology. 2022 May;75(5):1354-1355. PMID: 35194822

5. **Watkins PB.** Liver injury due to drugs and viruses: Mechanistic similarities and implications for AAV gene therapy. Invited Commentary. Clin Pharmacol. Ther. Published on line 12-12-21.

6. Paola Nicoletti, Harshad Devarbhavi, Ashish Goel, Radha Venkatesan, Chundamannil E. Eapen, Jane I. Grove, Samreen Zafer, Einar Bjornsson, M. Isabel Lucena, Raul J. Andrade, Munir Pirmohamed, Mia Wadelius, Dominique Larrey, Anke-Hilse Maitland-van der Zee, Luisa Ibanez, **Paul B Watkins**, Ann K. Daly and Guruprasad P. Aithal. Genetic risk factors in drug-induced liver injury due to isoniazid-containing anti-tuberculosis drug regimens. Clin Pharmacol and Ther. 2021 109(4):1125-1135. PMID: 33135175

7. Rachel J. Church and **Paul B. Watkins**. The challenge of interpreting alanine aminotransferase elevations in clinical trials of new drug candidates. Clin Transl Sci. 2021;14(2):434-436.

8. Khatri R, Kulick N, Rementer RJB, Fallon JK, Sykes C, Schauer AP, Malinen MM, Mosedale M, **Watkins PB**, Kashuba ADM, Boggess KA, Smith PC, Brouwer KLR, Lee CR. Pregnancy-Related Hormones Increase Nifedipine Metabolism in Human Hepatocytes by Inducing CYP3A4 Expression. J Pharm Sci. 2021 Jan;110(1):412-421 PMID: 32931777 **.**

9. **Watkins, PB**, Church, RJ, Li, JL, Knappertz, V. Cannabidiol and Abnormal Liver Chemistries in Healthy Adults: Results of a Phase 1 Clinical Trial. Clin Pharmacol Ther. 2021 May;109(5):1224-1231. PMID: 33022751

10. JJ Beaudoin, WJ Brock, **PB Watkins**, KLR Brouwer. Quantitative Systems Toxicology Modeling Predicts that Reduced Biliary Efflux Contributes to Tolvaptan Hepatotoxicity. Clinical Pharmacology & Ther. Clin Pharmacol Ther. 2021 Feb;109(2):433-442. PMID: 32748396

11. Li YJ, Phillips EJ, Dellinger A, Nicoletti P, Schutte R, Li D, Ostrov DA, Fontana RJ, **Watkins PB**, Stolz A, Daly AK, Aithal GP, Barnhart H, Chalasani N. Human Leukocyte Antigen B*14:01 and B*35:01 Are Associated With Trimethoprim-Sulfamethoxazole Induced Liver Injury. Hepatology. 2021 Jan;73(1):268-281. PMID: 32270503

12. **Watkins PB.** DILIsym: Quantitative systems toxicology impacting drug development. Current Opinions in Toxocology. In press, 2021

13. Church RJ, Schomaker SJ, Eaddy JS, Boucher GG, Kreeger JM, Aubrecht J, **Watkins PB**. Glutamate dehydrogenase as a biomarker for mitotoxicity; insights from furosemide hepatotoxicity in the mouse. PLoS One 2020 9;15(10):e0240562. PMID: **33035276**

14. Regev, A, Avigan, MI, Kiazand, A, Vierling, JM, Lewis, JH, Omokaro, SO, Di Bisceglie, AM, Fontana, RJ, Bonkovsky, HL, Freston, JW, Uetrecht, JP, Miller, ED, Pehlivanov, ND, Haque, SA, Harrison, MK, Kullak-Ublick, GA, Li, H, Patel, NN, Patwardhan, M, Price, KD, **Watkins, PB**, Chalasani, NP. Best practices for detection, assessment and management of suspected immune-mediated liver injury caused by immune checkpoint inhibitors during drug development. J Autoimmun. 2020 Nov;114:102514. Review. PMID: 32768244

15. Koido M, Kawakami E, Fukumura J, Noguchi Y, Ohori M, Yasunori N, Nicoletti P, Aithal GP, Daly AK, **Watkins PB,** Anayama H, Dragan Y, Shinozawa,Takebe T. Polygenic architecture informs potential vulnerability to drug-induced liver injury. Nat Med. 2020 Oct;26(10):1541-1548. PMID: 32895570

16. Smith, B, Rowe, J, **Watkins, PB**, Ashina, M, Woodhead, JL, Sistare, FD, Goadsby, PJ. Mechanistic Investigations support liver safety of ubrogepant. Toxicol Sci. 2020 Sep 1;177(1):84-93PMID: 32579200

17. **Watkins, PB**. DILIsym: Quantitative systems toxicology impacting drug development. Current Opinion in Toxicology. 2020, 23-24:67-73.

18. Konicki, R, Weiner, D, Patterson, JH, Gonzalez, D, Kashuba, A, Cao, YC, Gehi, AK, **Watkins, PB**, Powell, JR. Rivaroxaban Precision Dosing Strategy for Real World Atrial Fibrillation Patients. Clin Transl Sci Clin Transl Sci . 2020 Jul;13(4):777-784. PMID: 32267996**.**

19. Tyson RJ, Park CC, Powell JR, Patterson JH, Weiner D, **Watkins PB**, Gonzalez D. Precision Dosing Priority Criteria: Drug, Disease, and Patient Population Variables. Front Pharmacol. 2020 Apr 22;11;420. PMID: 32390828; PubMed Central PMCID: PMC7188913. Review.

20. Bruno, CD, Fremd, B, Church, RJ, Dale, AK, Aithal, GP, Bjornson, ES, Larrey, D, **Watkins, PB**, Chow, CR. HLA associations with infliximab-induced liver injury. Pharmacogenomics J. 2020 Oct;20(5):681-686. PMID: 32024945

21. Mosedale, M, **Watkins, PB**. Understanding Idiosyncratic Toxicity: Lessons Learned from Drug-Induced Liver Injury. J Med Chem 2020 Jun 25;63(12):6436-6461. PMID:32037821

22. **Watkins, PB**. Quantitative Systems Toxicology Approaches to Understand and Predict Drug-Induced Liver Injury. Clin in Liver Disease 2020 Feb;24 (1);49-60. Epub 2019 Nov 1. Review. PMID: 31753250

23. Grant Generaux, Vinal V Lakhani, Yuching Yang, Sashi Nadanaciva, Luping Qiu, Keith Riccardi, Li Di, Brett A Howell, Scott Q Siler, **Paul B Watkins**, Hugh A Barton, Michael D Aleo, Lisl KM Shoda. Quantitative systems toxicology (QST) reproduces species differences in PF-04895162 liver safely due to combined mitochondrial and bile acid toxicity. Pharmacol Res Perspect, 2019 Dec;7(6):e00523. PMID: 31624633; PubMed Central PMCID: PMC6785660

24. **Watkins, PB**. Idiosyncratic drug-induced liver injury in patients: Detection, severity assessment, and regulatory implications. Adv Pharmacol. 2019;85:165-193. Review. PMID: 31307586

25. Prabhavathi Fernandes, David Pereira, **Paul Brent Watkins**, Daniel Bertrand. Differentiating the Pharmacodynamics and Toxicology of Macrolide and Ketolide Antibiotics. J Med Chem. 2020 Jun 25;63(12):6462-6473. PMID: 31644280

26. Goadsby, PJ, Tepper, SJ, **Watkins, PB**, Ayele, G, Miceli, R, Butler, M, Severt, L, Finnegan, M, Szegedi, A, Trugman, JM, Jakate, A. Safety and tolerability of ubrogepant following intermittent, high-frequency dosing: Randomized, placebo-controlled trial in healthy adults. Cephalalgia. 2019 Dec;39(14):1753-1761. PMID: 31537107; PubMed Central PMCID: PMC6900570

27. Mosedale, M, Cai, Y, Eaddy, JS, Corty, RW, Nautical, M, **Watkins, PB**, Valdar, W. Identification of Candidate Risk Factor Genes for Human Idelalisib Toxicity Using a Collaborative Cross Approach. Toxicol Sci. 2019 Dec 1;172(2):265-278. PMID: 31501888

28. Yi-Ju Li, Andrew Dellinger, Paola Nicoletti, Robert Fontana, **Paul Watkins**, Huiman Barnhart, Elizabeth Phillips, Naga Chalasani. HLA B* 14: 01 is associated with Trimethoprim-sulfamethoxazole induced liver injury. J of Hepatology 2019 April 1; 70:e419-E419.

29. Fu, D, Cardona, P, Ho, H, **Watkins, PB**, Brouwer, KLR. Novel Mechanisms of Valproate Hepatotoxicity: Impaired Mrp2 Trafficking and Hepatocyte Depolarization. Tox Sci. 2019 July 31;171(2):431-42. [Epub ahead print]. PMID: 31368504

30. Sharin Roth, Mark Avigan, David Bourdet, David Brott, Rachel Church, Ajit Dash, Douglas Keller, Philip Sherratt, **Paul B. Watkins**, Lucas Westcott-Baker, Silvia Lentini, Michael Merz, Lila Ramaiah, Shashi Ramaiah, Ann Marie Stanley, and John Marcinak. Next Generation DILI Biomarkers: Prioritization of Biomarkers for Qualification and Best Practices for Biospecimen Collection in Drug Development. Clinical Pharm & Ther. 2020 Feb;107(2):333-346.

31. Raul J. Andrade, Naga Chalasani, Einar S. Björnsson, Ayako Suzuki, Gerd A. Kullak-Ublick, **Paul B. Watkins**, Harshad Devarbhavi, Michael Merz, Maribel I. Lucena, Neil Kaplowitz, Guruprasad P. Aithal. Drug-induced liver injury. Nat Rev Dis Primers. 2019 Aug 22;5(1):58. Review. PMID: 31439850

32. Holman, NS, Church, RJ, Nautiyal, M, Rose, KA, Thacker, SE, Otieno, MA, Wolf, KK, LeCluyse, E, **Watkins, PB**, Mosedale, M. Hepatocyte-Derived Exosomes Promote Liver Immune Tolerance: Possible Implications for Idiosyncratic Drug-Induced Liver Injury. Tox Sci. 2019 Aug 1;170(2):499-508. PMID: 31093666

33. Bonkovsky, HL, Severson, T, Nicoletti, P, Barnhart, H, Serrano, J, Chalasani, N, Fontana, RJ, **Watkins, PB**, Navarro, V, Stolz, A, Daly, AK, Aithal, GP, Odin, J, US DILIN Investigators. Genetic Polymorphisms Implicated in Non-Alcoholic Liver Disease [NAFLD] or Selected other Disorders have no Influence on Drug-Induced Liver Injury [DILI]. Hepatol Commun. 2019 Aug;3(8):1032-1035. PMID: 31388624; PubMed Central PMCID: PMC6671782

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Non-peer reviewed journals

1. **Watkins, PB** and Lake, F. Looking to the future of drug-induced liver injury: An interview with Dr. Paul B. Watkins, MD. Future Sciences. 2017.

Book Chapters:

1. **Watkins, PB.** Drug-Induce Liver Injury. 27th edition of Goldman-Cecil textbook of Medicine. Elsevier. In press

2. **Watkins PB.** Quantitative Systems Toxicology and Drug Development: The DILIsym Experience. Ed: Jane Bai (FDA). Springer. In press

3. **Watkins, PB.** "Quantitative Systems Toxicology Approaches to Understand and Predict Drug-Induced Liver Injury" Clinics in Liver Disease, Elsevier, in press.

4. **Watkins, PB.** "Idiosyncratic drug-induced liver injury in patients: Detection, severity assessment, and regulatory implications", in Advances in Pharmacology, Drug-Induced Liver Injury, Volume 85, 2019 (Chapter Six, p. 165 - 194).

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6. **Watkins, PB** and Mosedale, M. 12th edition. "Mechanisms of drug induced liver disease" In: Schiff's Diseases of the Liver, Eds. Schiff, ER, Maddrey, WC, Sorrell, MC. John Wiley & Sons Ltd. 2017. Previous editions: Lippincott - Williams and Wilkins. (Book chapter).

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INVITED TALKS AT NATIONAL AND INTERNATIONAL MEETINGS:

1. 6/15/22 – Medical University of South Carolina Grand Rounds
   Title: Why good drugs are sometimes bad for the liver.

2. 1/22/22 – FDA Guest Lecture series.
   Title: Quantitative Systems Toxicology – Current and future impact on drug development.The DILI-sim Initiative: Applying Quantitative Systems Toxicology to understand, predict, and prevent DILI”.

3. 12-11-21 – American Association for the Study of Liver Diseases webinar.
   Title: The DILI-sim Initiative: Applying Quantitative Systems Toxicology to understand, predict, and prevent DILI”.

4. 12/4/21 - Shanghai International Symposium for Liver Disease
   Shanghai, CHINA – Invited speaker – Plenary Session (>22,000 on ZOOM)
   Title: New Approaches to assess and manage Drug-Induced Liver Injury

5. 2/4/21 - Asia Pacific Association for the Study of Liver Disease annual meeting
   State of the Art Plenary Lecture
   Title: Understanding Idiosyncratic Drug Reactions : Lesson Learned from Drug-Induced Liver Injury

6. 12/16/20 – ROSA International Seminar Series
   Impact of Modeling & Simulation in Drug Development
   Title: QST and the Transformation in Safety Assessment

7. 12/12/20 - Shanghai International Symposium for Liver Disease
   Shanghai, CHINA – Invited speaker – Plenary Session
   Title: New insights into Drug-Induced Liver Injury

8. 11/14/20 – American Association of the Study of Liver Diseases Annual Postgraduate Course
   Title: DILI as an immune disease; Implications for management.

9. 10/08/2020 - Global Antibiotic Research & Development Partnership (GARDP)
   Online Webinar: Exploring Safety Issues in Antimicrobial Drug Development
   Title: Quantitative Systems Toxicology and Antibiotic Development

10. 12/7/2019 – 2019 Shanghai International Symposium for Liver Disease
    Shanghai, CHINA – Invited speaker – Plenary Session
    Title: Update on the U.S. DILIN Network, followed by second talk,

11. 11/9/2019 – AASLD Meeting

Boston, MA
Abstract: Discovery of ERAP2 Gene Expression as a risk factor for drug-induced liver injury due to amoxicillin-clavulanic acid

12. 11/8/2019 – AASLD Early Career Investigator Mentor
    Boston, MA
    Topic: Hepatotoxicity SIG – Early Career Mentoring Session

13. 11/9/2019 – AASLD Early Morning Workshop
    Boston, MA
    Topic: EMW 9: Genetic Predisposition to Hepatotoxicity

14. 7/24/2019 – American Society for Cellular and Computational Toxicology (ASCCT) Webinar – Invited Speaker
    Title: Using Quantitative Systems Toxicology (QST): Improving the safety of drugs while reducing animal testing

15. 5/9/2019 – FDA Office of Computational Sciences and Liver Toxicity Work Group Innovation Forum on DIA-ASA Liver Safety Explorer and Clinical Workflow for Interactive Evaluation of Safety
    Silver Springs, MD
    Invited Speaker: DIA-ASA Liver Safety Tool, Utility to a Clinical Hepatologist

16. 5/7 – 5/8/2019 – AASLD/FDA DILI Conference: Addressing Gaps in the Current Guidance: Assessing DILI with Novel Treatments or Preexisting Liver Disease in Clinical Trials
    Hyattsville, MD
    Invited Speaker: Assessing and Managing DILI Risk in Trials: A Consultant's Perspective
    Co-Organizer of the event
    Co-Moderator of Session II: Tools for Pre-marketing Assessment of DILI Liability: What do we Need?

17. 3/11/2019 - The Physicians Committee for Responsible Medicine and AxoSim Technologies meeting: Nonclinical Innovation and Patient Safety Initiative (NIPS)
    Baltimore, MD
    Invited Participant

18. 12/2/18 – Chinese Association for the Study of Liver Diseases
    Shanghai, China
    Invited Speaker: Quantitative Systems Toxicology Provides New Insights into DILI

19. 11/11/2018 – AASLD Meeting
    San Francisco, CA
    Identification of a PTPN22 Missense Variant as a General Genetic Risk Factor for Drug-Induced Liver Injury

20. 11/7/2018 – AAPS PharmaSci 360
    Washington, DC
    Invited Speaker: Mechanisms Underlying Species Differences in Hepatotoxicity

21. 5/22-5/23/2018 – NIH NCATS Translator May Hackathon
    Invited SME (Subject Matter Expert) on DILI
    Bethesda, MD

22. 4/24/18 - ASPET 2018 Annual Meeting
    San Diego, CA
    Presented with the Division for Toxicology Career Award

23. 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

24. 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

25. 10/20/2017 – AASLD Hepatoxicity Special Interest Group (SIG) Symposium at the 2017 Liver meeting
    Washington, DC
    Co-moderator: Controversial Issues – Clinical Cases, Monitoring, and Regulatory Issues.

26. 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

27. 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?

28. 8/22/2017- 254 American Chemical Society National Meeting
    Washington, DC
    Keynote Speaker: Understanding hepatoxicity: Man, to mouse to computer

29. 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

30. 6/13/2017 – World Preclinical Congress
    Boston, MA
    Invited Speaker: Predicting Liver Safety Liabilities in New Drug Candidates: Are We There Yet?

31. 6/6/2017 – FDA C-Path DILI Conference XVII
    Bethesda, MD
    Meeting Organizer and Invited Speaker: DILIsym Initiative

32. 5/8/2017 – AASLD at Digestive Disease Week
    Chicago, Il
    State of the Art Lecture: DILI: Is this Pill Safe to Swallow?

33. 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

34. 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

35. 1/9/2017 – FDA NCTR: The Liver Toxicity Working Group Workshop
    Little Rock, AR
    Topic: Drug-Induced Liver Injury: Crosstalk among Clinicians, Toxicologists, and Regulators
    Invited speaker via WebEx: "Quantitative Systems Toxicology Approaches to Assess Liver Safety"

36. 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

37. 11/16/2016 – World Preclinical Congress Europe
    Lisbon, Portugal
    Keynote Presentation: Using Quantitative Systems Toxicology (QST) to Assess and Manage Drug Safety
    Moderator of Panel Discussion: Breaking Down Silos: Updates on New Initiatives, Consortia & Collaborations

38. 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

39. 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

40. 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"

41. 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

42. 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

43. 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

44. 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

45. 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

46. 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

47. 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

48. 10/21/15 – 20th North American ISSX Meeting
    Orlando, FL
    Plenary Speaker: Understanding Idiosyncratic Hepatoxicity: From Cage to Clinic

49. 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

50. 8/21/15 – FDA, C-Path Symposium: Evidentiary Considerations for Integration of Biomarker in Drug Development

Silver Spring, MD
Invited panelist

51. 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

52. 6/23/15 - 13th European ISSX Meeting
    University of Strathclyde
    Glasgow, Scotland
    Invited Speaker: Systems Modeling Approaches to Predict Idiosyncratic DILI

53. 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 Hepatoxicity in Drug Development

54. 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

55. 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

56. 11/9/2014 – AASLD – The Liver Meeting
    Boston, MA
    Invited Speaker: GWAS and Exome Chips in DILI: What have we learned?

57. 11/9/2014 – AASLD – The Liver Meeting
    Boston, MA
    Invited Speaker: Causality Assessment and Autoimmunity in Hepatotoxicity

58. 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

59. 10/9/2014 – Falk Workshop, The Challenge of drug-induced liver injury (DILI)
    Freiburg, German
    Invited speaker: How to diagnose and exclude DILI

60. 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

61. 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

62. 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

63. 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

64. 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

65. 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

66. 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?

67. 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

68. 10/2/2013 – 10th International ISSX Meeting
    Toronto, CA
    Invited Speaker: Insights from Healthy Volunteer Studies

69. 9/26/13 – FDA – Critical Path Institute Modeling and Simulation for Medical Products Workshop
    Invited Speaker: Collaborative Approaches to Mechanistic Modeling *and* workshop participant

70. 9/17/13 – MRC Centre for Drug Safety Science, University of Liverpool "In Vitro Endpoints and Markers of Hepatotoxicity Workshop"
    Liverpool, UK
    Invited Keynote Address: Drug-induced liver injury

71. 9/8/13 – American Chemical Society Fall Meeting
    Indianapolis, IN
    Invited Speaker: Biomarkers for the diagnosis and management of drug-induced liver injury

72. 9/4/13 – AbbVie Seminar
    Waukegan, IL
    Invited Speaker: Hepatoxicity in Drug Development

73. 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

74. 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

75. 6/4/13 – 6/5/13 – World Pharma Congress
    Philadelphia, PA
    Keynote Address: Is Drug Safety Really a Problem in 2013?
    Invited Speaker: Practical Applications of DILIsym™, a Mechanistic Model of Drug-induced Liver Injury

76. 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

77. 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

78. 3/10/13 – Annual FDA Hepatotoxicity Meeting: Detecting and Evaluating DILI
    Hyattsville, MD
    Invited Speaker: The Liver Safety Consortium

79. 3/8/13 – ASCPT Annual Meeting
    Indianapolis, IN
    Invited Speaker: Proteomics, Metabolomics and DILI Biomarkers

80. 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

81. 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

82. 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

83. 12/5/12 – Drug Information Association (DIA)
    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

84. 11/9/12 - International Liver Safety Workshop: Liver Safety Assessment in Clinical Drug Development: Best Practices Workshop
    Boston, MA
    Co-Organizer and Moderator

85. 10/30/12 – Research Triangle Institute International
    RTP, NC
    Invited speaker: Why Good Drugs are Sometimes Bad for the Liver

86. 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

87. 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

88. 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

89. 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

90. 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 Hepatoxicity in Diabetic Drug Development: The Legacy of Troglitazone

91. 6/28/12 – Sino-American Symposium on Clinical and Translational Medicine (SAS-CTM)
    Shanghai, China
    Invited Speaker: Drug Induced Liver Injury

92. 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

93. 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

94. 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

95. 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

96. 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

97. 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?

98. 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

99. 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

100. 1/26/12 – National Institutes for Health
    RTP, NC
    Invited Speaker: Recent Advances in understanding Idiosyncratic Hepatoxicity

101. 11/5/11 – AASLD The Annual Liver Meeting 2011
    San Francisco, CA
    Invited Speaker: Drug-induced Liver Injury
    Special Interest Group Program: The Role of Adaptive Immunity in DILI

102. 10/26/11 – FDA/CDER Seminar Series
    Silver Springs, MD
    Invited Speaker: Why Good Drugs are Sometimes Bad for the Liver

103. 10/17/11 – Acute Liver Failure Study Group - Pathogeneses of Liver Injury Forum
    Dallas, TX
    Invited Speaker: GWAS Studies in DILIN

104. 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

105. 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

106. 8/30/11 – 242nd American Chemical Society National Meeting
    Denver, CO
    Invited Speaker: Idiosyncratic Drug Induced Liver Injury: From Man to Mouse to Computer

107. 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 Post market Surveillance

108.6/8/11 – World Pharma Congress: New Assays and Tools for Predicting Hepatotoxicity
Philadelphia, PA
Invited Speaker: Mechanistic Insights into Hepatoxicity

109.5/15/11 – American Thoracic Society Annual Meeting
Denver, CO
Invited Speaker: Idiosyncratic Hepatotoxicity

110.5/9/11 – AGA: Digestive Disease Week 2011
Chicago, IL
Invited State-of-the-Art Lecture: When Good Drugs are bad for the Liver

111.4/13/11 – 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

112.3/23/11 – 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

113.3/7/11 – 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

114.2/27/11 – Liver Disease Day
Indian Wells, CA
Invited Speaker: Why good drugs can be bad for the liver

115.12/16/10 – 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

116.11/9/10 - Mitigating Safety Risks in Early Clinical Development & Post-Approval Drug Development
Philadelphia, PA
Invited Speaker: Idiosyncratic Liver Injury: Challenges and Approaches

117.11/8/10 – 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

118.9/5/10 – International Society for the Study of Xenobiotics 9th International Meeting

Istanbul, Turkey
Invited Speaker: Understanding Idiosyncratic Hepatotoxicity: From Man to Mouse to Computer

119.6/16/10 – 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

120.6/8/10 – Delaware Valley Drug Metabolism Discussion Group Rozman Symposium
Langhorne, PA
Invited Speaker: Why Good Drugs are Sometimes Bad for the Liver

121.5/22/10 – 2010 Bio-X International Translational Medicine Symposium
Shanghai, China
Invited Speaker: Predicting and understanding drug-induced liver injury: an emerging role for personalized medicine

122.5/15/10 - Tuberculosis Trials Consortium (TBTC) Semi-Annual Group Meeting
New Orleans, LA
Invited Speaker: TB and hepatotoxicity: A great opportunity for biomarker discovery

123.4/26/10 – 2010 Economic Development Summit on Seizing Economic Opportunity through the Botanical Medicine and Integrative Health Industry
Asheville, NC
Invited speaker: Safety of Natural Products: A Competitive Advantage for NC

124.3/25/10 – 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

125.3/16/10 – Serious Adverse Event Consortium Phenotyping Standardization Project Consensus Conference
Hinzton, Cambridge, UK
Co-Chair: DILI Expert Working Group

126.3/10/10 - Annual meeting of the Society of Toxicology
Salt Lake City, UT
Invited speaker: Novel Research Approaches and Animal Models in Translational Toxicology

127.3/4/10 – Research Triangle Park Drug Metabolism Discussion Group - Winter Symposium
RTP, NC
Plenary talk: Impact of Drug Metabolism Science in the 21st Century

128.2/26/10 – FDA Institute of Medicine, Forum on Drug Discovery, Development and Translation
Washington, DC

Invited talk: The Hamner-UNC Institute for Drug Safety Sciences

129.6/30/09 – Center for Drug Safety Sciences Inaugural Symposium
Liverpool, UK
Invited talk: Biomarkers for Drug Induced Liver Injury

130.6/23/09 – Drug Information Association Annual Meeting
San Diego, CA
Invited talk: The Institute of Medicine report of biomarkers for drug safety

131.5/31/09 – American Gastroenterology Association Annual meeting
Chicago, IL
Invited speaker at annual course: Drug Induced Liver Injury

132.4/8/09 – FDA/Pharma/AASLD Hepatoxicity Symposium
Silver Spring, MD
Invited talk: Update on the IOM and DILIN research agendas
Session Chairman

133.3/20/09 – American Society for Clinical Pharmacology and Therapeutics
Washington, DC
Invited Talk: Translational research approaches to improve drug safety

134.1/25/09 – Molecular Medicine Tri-Conference
San Francisco, CA
Invited Talk: Novel preclinical approaches to predict drug induced liver injury
Session Chairman

135.1/16/09 – National Center for Toxicologic Research
Little Rock, AR
Invited talk: Novel approaches to study acetaminophen toxicity

136.12/9/08 – New York Academy of Sciences symposium on Drug Safety
New York, NY
Invited talk: Novel approaches to understanding drug induced liver injury

137.12/1/08 – NIH Conference on Nomenclature in Drug Induced Liver Injury
Bethesda, MD
Invited talk: Development of biomarkers for liver safety
Chair of afternoon session

138.11/6-11/7/08 – CBI Symposium on Hepatotoxicity
Philadelphia, PA
Co-chair of Conference
Invited Speaker: Use of clinical trials to identify novel biomarkers of hepatotoxicity

139.11/1/08 - Annual meeting of the American Association for the Study of Liver Diseases
San Francisco, CA
Breakfast workshop: Drug Induced Liver Disease

140.10/28/08 – 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

141.10/24/08 – Institute of Medicine Workshop on Biomarkers for Drug Safety
Washington, DC
Invited Presentation: Hepatotoxicity Biomarker White Paper
Co-chair, Hepatotoxicity Biomarkers Discussion Session

142.6/5/08 – 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

143.3/26-3/27/08 - 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"

144.6/6/07 – New England Drug Metabolism Discussion Group
Boston, MA
Dinner Speaker: Hepatotoxicity: Why preclinical models fail

145.12/11/06 – NIGMS workshop: Understanding the genetic basis of medication safety
Bethesda, MD
Invited speaker – Idiosyncratic drug induced liver injury

146.8/15/06 – NIH Roadmap meeting on Predictive Models for Drug Safety Assessment
NIH Campus, Lister Auditorium
Keynote Address: Idiosyncratic hepatotoxicity: Why current animal preclinical models fail?

147.12/01/05 - NIEHS Extramural Administrators Workshop
Wilmington, NC
Keynote Address: Human Experimentation in Environmental Health Research

148.10/31/05 – 11/1/05 – NIEHS Center Directors Meeting
Vanderbilt, TN
Member Panel Discussion: P30 Clinical Research in Environmental Health Sciences

149.9/29/05 – 9/30/05 - IBC Conference on Signal Detection and Risk Assessment
Washington, DC
Invited Speaker: Update on the Drug Induced Liver Injury Network (DILIN)

150.9/16 – 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

151.8/24/05 – The International Society for Pharmacoepidemiology
Nashville TN
Invited speaker
Topic: The Drug Induced Liver Injury Network (DILIN)

152. 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

153. 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

154. 11/9/04 – Sixth International Workshop on the Pharmacodynamics of Anti-Cancer Agents
Venice, Italy
Invited talk: Metabolism in the Gut

155. 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

156. 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

157. 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

158. 10/30/04 - Annual Meeting of the American Association for the Study of Liver Diseases
Boston, MA
Meet the Professor Luncheon: Drug induced transaminitis

159. 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

160. 6/21/04 - 2004 Pharmacogenomics Conference
Nashville TN
Invited Talk: Genomic Approaches to Understanding Drug Induced Liver Disease

161. 6/14/04 – Annual meeting of The Society of Toxicologic Pathology
Salt Lake City, UT
Keynote Address: Drug Induced Liver Disease – A Clinician's Perspective

162. 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

163. 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

164. 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

165. 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

166. 7/14/03 – International Food Technology meeting
Chicago, IL
Invited talk: The Role of Furocomarins in Grapefruit juice: drug Interactions

167. 7/13/03 – Drug Metabolism Gordon Conference
Holderness, NH
Discussion Leader: Clinical Aspects of Hepatotoxicity
Invited Speaker: Acute hepatocellular injury due to drugs

168. 5/6/03 – Tools for Pre-Approval Drug Safety
Rockville, MD
FDA course for medical reviewers
Invited talk: Hepatotoxicity and Drug Safety Evaluation

169. 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

170. 2/23-24/03 – Co-Chair Symposium on Drug Induced Liver Disease
Washington, DC
Invited Talk: Pharmacogenomic Approaches

171. 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

172. 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

173. 7/22/02 – American Society of Pharmacology and Therapeutics
Washington, DC
Invited Talk: Citrus juice / drug interactions

174. 5/30/02 – Centers for Education and Research in Therapeutics Annual Meeting
Chapel Hill, NC
Invited Talk: Pharmacogenomics and Adverse Events

175. 2/06/02 – Toxicology Forum
Washington, DC
Invited talk: Mechanism-based inactivation by fruit juices

176. 10/10/01 – International Society for the study of Xenobiotics

Munich, Germany
Invited Talk: Role of Transporters in Oral Availability

177. 9/17/01 The Benzon Symposium No.48
Drug Metabolism: Regulation and Importance
Copenhagen, Denmark
Invited Talk: Probe based tests of CYP3A enzymes

178. 7/10/01 – Toxicology Forum
Aspen, CO
Invited talk: Mechanism of Drug Induced Liver Disease

179. 3/7/01 – American Society for Clinical Pharmacology and Therapeutics
Orlando, FL
Invited talk: Drug Interactions with Herbal Products and Foods

180. 2/13/01 – FDA/Pharma Symposium on Drug Induced Liver Injury
Rockville, MD
Invited Talk: Pharmacogenetic/Pharmacogenomic approaches

181. 11/14/00 – European Society for Clinical Pharmacology
Basel, Switzerland
Invited Talk: Diet/Drug Interactions

182. 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

183. 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

184. 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

185. 7/16/00 International Microsomes and Drug Oxidations Symposium
Stresa, Italy
Chairman, Session entitled, Extrahepatic Metabolism

186. 6/19/00 IV International Symposium on Drug Interactions
Baltimore, MD
Invited talk: Citrus juices and transporters in the small bowel

187. 6/12/00 International Society for the Study of Xenobiotics
Drug Metabolism Workshop
Dundee, Scotland
Invited talk: Role of transporters in drug disposition

188. 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

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
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
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

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 P450IIIA 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 P450IIIA 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 P450IIIA; 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

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 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
4/8/2020

University of North Carolina at Chapel Hill
Drug Metabolism Module graduate course (DPMP 810/815) – Dr. Philip C. Smith
Chapel Hill, NC
Topic: Drug Induced Liver Injury, DILI
3/7/2019

University of North Carolina at Chapel Hill
Advanced Toxicology Course (TOXC_707) – Dr. James A. Swenberg
Chapel Hill, NC
Topic: Why good drugs are sometimes bad for the liver
2/21/19

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: Hepatoxicity 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

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
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
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
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

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
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

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
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
Division of Clinical Pharmacology
Pittsburgh, PA
5/6-5/7/92
Topic: Clinical relevance of inter-patient differences in P450IIIA 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 P450IIIA

Vanderbilt University
Pharmacology Seminar
Nashville, Tennessee
9/10/90
Topic: Noninvasive Assays of P450IIIA 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
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

Campbell Faculty Mentoring:

Amanda Anne Seyerle, Assistant Professor, UNC School of Pharmacy

Doctoral Thesis Committees:

1). William Alan Murphy	2020-present
2). Jessica Lee Murray	2019-present
2). Aaron S. Devanathan (chair)	2019-present
3). James John Beaudoin	2015-2020
4). Izna Ali, PharmD	2014-2019
5). Cen Guo	2013–2018
6). Leah Norona	2015-2017
7). Natalie Holman	2012-2016
8). Kyunghee Yang	2011-2014
9). Latoya Griffin	2009-2012
10). Tracy Marion	2008-2010
11). Alison Hege Harrill	2006-2008
12). Matthew Troutman	2002
13). Keith Hoffmaster	2001
14). Yuan Zing	1998
15). Ching Ling	1996
16). 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:

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). Niyati Vachharajani	2019-present
2). Christina Battista **ORISE FELLOW**	2015-2019
2). Kyunghee Yang **ORISE FELLOW**	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:

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 – 1/1/18
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
15). D. Lans Taylor, PhD, Director, University of Pittsburgh Drug Discovery Institute, Distinguished Professor and Allegheny Foundation Professor of Computational & Systems Biology, 9/10/18
16). Tanzir Mortuza, PhD, Doctoral Student, University of Georgia, 6/14/18
17). Nader Hamzavi, PhD, Research Scientist, University of Massachusetts, 10/30/18

GRANT SUPPORT:

Current Grant and Research Support:

PI or Co-PI:

1). NIH -2UO1 DK065201-16
Title: “Drug Induced Liver Injury Network”
PI: Paul B. Watkins
Project period: 9/1/18 – 8/31/23
Total Direct Cost:
$1,462,870.00
The major goals of this project are to understand and predict liver toxicity produced by drugs and herbal products. Dr. Watkins directs one of 8 clinical centers in this nationwide network. He is chair of Executive, Steering, and Genetics Committees for this network.

2). NIH/NIGMS, 2T32GM086330-06
Title: “UNC-Duke Collaborative Clinical Pharmacology Postdoctoral Training Program” PIs: Benjamin, Brouwer and Watkins (Multiple PIs)

Project Period: 7/1/11 – 6/30/2021
Total Direct cost: $2,505,858.00
The major goals of this project are to develop innovative clinical pharmacologists who will conduct cutting-edge research and mentor the next generation of clinician- scientists in clinical pharmacology

3). Burroughs-Welcome Foundation Innovation in Regulatory Science Award
Transfer from Merrie Mosdale
PI:
~$100,000 for completion of mouse spheroid studies.

Co-Investigator:

1). NICHD, A20-1100
Title: Mechanisms of Altered Hepatic Drug Metabolism and Transport in Pregnancy
PI: Craig Lee
Project period (4/1/20 – 3/31/24)
Total Direct Costs: $1,700,000.00

2). 1OT2TR003430-01 (MPI: Ahalt, Krishnamurthy);
ICEES+ Knowledge Provider: Leveraging Open Clinical and Environmental Data to Accelerate and Drive Innovation in Translational Research and Clinical Care
Total direct cost: $2,934,312

Past grant and Research Support:

3T32GM086330-10S1
Title: UNC-Duke Collaborative Clinical Pharmacology Postdoctoral Training Program-Evaluation Supplement
PIs: Brouwer, Cohen-Wolkowiez, Watkins.
Project period: 07/01/2020 – 06/30/2021
Total Direct cost: $86,400
The goal is to improve the evaluation of all GM T32s on campus.

PharmAlliance Grant PA2018 TierA_ID27 (Monash-UNC)
Title: “Novel approach to predict drug-induced liver injury using metabolomics and systems toxicology
PI: Creek; (Monash), Brouwer, Mosedale, and Watkins (UNC) Project Period: 11/18-10/19

NIH Office of the Director: 1-R21-OD028216-01
Development of an in vitro mouse genetic reference platform to improve preclinical drug safety assessment
PI: Merrie Mosedale
Project Period: 8/15/20 – 7/31/21

Total Direct costs: $223,571.00

RX03712214 (PI: Watkins)
Eshelman Institute for Innovation Award
Title:" An Exosome-Based Assay for Predicting Idiosyncratic Drug-Induced Liver Injury"
PI: Watkins
Project Period: 1/1/18-12/31/18- extended to 6/30/19
$115,167

1 R44 GM123796-01
Subaward SciKon Innovation
Title: "Standardization of a fluidic in vitro exposure system for IVIVE predictive toxicity data"
The 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.
PI: Mosedale
Project Period: 9/17 - 2/19
$48,167

NIH -UO1 DK065201
Title: "Drug Induced Liver Injury Network"
PI: Paul B. Watkins
Project period: 9/1/13 – 8/24/2018
Total direct cost: $1,250,000
Effort: 20%

Research Services Agreement, Allecra Therapeutics GmbH
Title: "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
PI: Mosedale
Project Period: 7/17 - 12/17
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Research Funding Agreement, Wapta, LLC
Title: "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
PI: Mosedale. Role: Investigator
Project Period: 4/17 - 4/19
$80,000

Funded Research Agreement, Gilead Sciences, Inc.
Director: Watkins
Title: "A research plan to identify mechanisms underlying liver injury due to idelalisib"
Project Period: 10/16 - 9/17
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
Title: “Development of an in vitro model for compound-induced hepatic fibrosis”
Project period: 5/16 - 8/17

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”
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

NIH, R32 DK09280-02
Title: “Human intestinal flavin monoxygenases”
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.
Title: “Noninvasive Assays of P450IIIA Enzymes in Man”
Total Project Period: 3/1/92 - 3/1/97
Total Direct Costs: $625,034
Annual Direct Costs: $120,000

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