



UNIVERSITY OF MINNESOTA

College of Pharmacy

DEPARTMENT OF EXPERIMENTAL AND CLINICAL PHARMACOLOGY

2013 Annual Report



DEPARTMENT OF
EXPERIMENTAL AND CLINICAL PHARMACOLOGY

2013 Annual Report

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The University's mission, carried out on multiple campuses and throughout the state, is threefold: research and discovery, teaching and learning, and outreach and public service. The University of Minnesota shall provide equal access to and opportunity in its programs, facilities, and employment without regard to race, color, creed, religion, national origin, gender, age, marital status, disability, public assistance status, veteran status, sexual orientation, gender identity, or gender expression.

This publication is available in alternative formats upon request. Direct requests to Erin McGonagle, Department of Experimental and Clinical Pharmacology, mcgo0064@umn.edu, 612-624-7639.

The mission of the Department of Experimental and Clinical Pharmacology is to discover, disseminate, and apply new knowledge related to safe, effective, and economical medication use in patients.



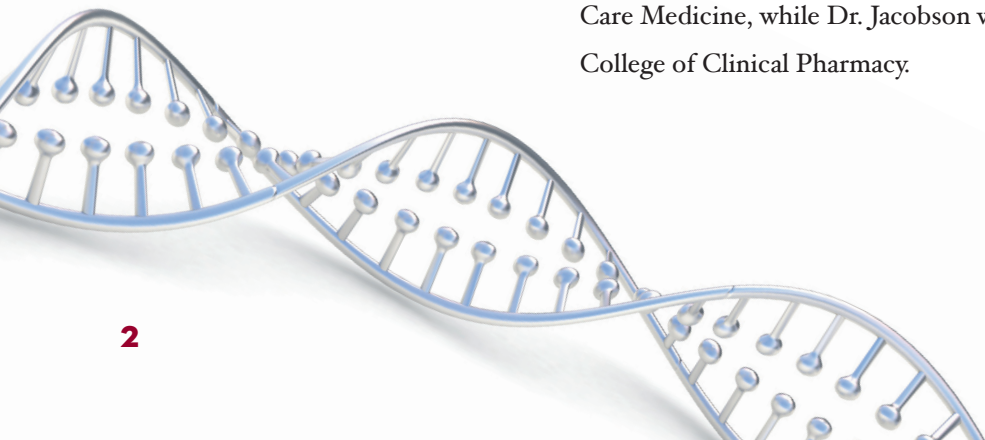
DEAR COLLEAGUES AND FRIENDS,

Without a doubt, the quality of a department depends upon its members: their innovative and rigorous research work, their leadership and service within the profession, the passion and excellence they bring to training the next generation of thinkers and practitioners. I am proud to say that the Department of Experimental and Clinical Pharmacology (ECP) comprises many such renowned investigators and scholars.

ECP also thrives because its members possess a range of experience and expertise. The decades of scholarship of our professors, the fresh perspectives of our junior faculty, along with the proven excellence of our research and administrative staff, all contribute to our department's standing as one of the top programs of its kind in the nation.

This past year has been one of expansive thinking and planning for ECP. Department members have seized opportunities to form new relationships with international peers from England to India to Singapore. (Given that funded research work is increasingly collaborative and studies can involve multiple sites and institutions, developing partnerships is an important ongoing objective.) New sponsored projects by faculty researchers were begun in areas as diverse as Alzheimer's disease, cognitive responses to drugs, and tobacco dependence, to name but a few. Lastly, in order to build upon the existing expertise of our renowned faculty, the department launched national searches for two new faculty positions.

We also congratulate two ECP faculty members who were promoted in 2013: Debra J. Skaar from assistant professor to associate professor, and Pamala A. Jacobson from associate professor (tenured) to professor (tenured). Each received significant external recognition for sustained excellence in their fields: Dr. Skaar was awarded Fellowship in the American College of Critical Care Medicine, while Dr. Jacobson was awarded Fellowship in the American College of Clinical Pharmacy.



Teaching, within the professional program and of our graduate students, continues to be a significant part of ECP's role within the College. The first year of a new curriculum was launched for the incoming class of Pharm.D. students in Fall 2013. Meanwhile, ECP faculty joined colleagues in other departments to design coursework for subsequent years. This substantial effort seeks to improve upon our current outstanding program, providing students a strong scientific foundation and preparing them for the collaborative, interdisciplinary work of tomorrow's health care team.

Our distinguished graduate program, which trains future leaders of clinical and translational research within human pharmacology and therapeutics, gained new leadership this year in Dr. Angela Birnbaum and Dr. Marnie Peterson, named director and associate director of graduate studies, respectively. In 2013, ECP graduate students presented research abstracts at national conferences, had publications accepted in peer-reviewed journals, and won competitive fellowships to support their graduate research. Students also had the opportunity to meet with an array of guest speakers brought in by the department who shared their expertise on topics such as antiretroviral agents used in the treatment of HIV infection, warfarin pharmacogenetics in under-represented populations, and pharmacokinetic/pharmacodynamic approaches to superbugs.

I am pleased to present you with this 2013 Annual Report. More of our department successes from the last year are cataloged in the pages that follow. I invite you to read through the diverse array of accomplishments that establish our department as a leading group of translational scientists in the discipline of experimental and clinical pharmacology.



Robert J. Straka, Pharm.D.
Professor and Department Head



FACULTY

Angela K. Birnbaum, Ph.D.
*Associate Professor; Director of
Graduate Studies*

Richard C. Brundage, Ph.D.,
Pharm.D.
Professor

Scott A. Chapman, Pharm.D.
Associate Professor

James C. Cloyd, Pharm.D.
*Professor; Weaver Endowed Chair in
Orphan Drug Development*

Jeannine M. Conway, Pharm.D.
*Assistant Professor; Director of Applied
Learning*

Esam El-Fakahany, Ph.D.
*Professor; Associate Dean for
Research and Graduate Studies*

Cynthia R. Gross, Ph.D.
Professor

David R. Guay, Pharm.D.
Professor Emeritus

Pamala A. Jacobson, Pharm.D.
Professor

L'Aurette A. Johnson, Ph.D.
Assistant Professor

Mark N. Kirstein, Pharm.D.
Associate Professor

Michael Kotlyar, Pharm.D.
Associate Professor

Jatinder Lamba, Ph.D.
Associate Professor

Vishal Lamba, Ph.D.
Assistant Professor

Ilo E. Leppik, M.D.
Professor

Ling Li, Ph.D.
*Professor; VFW Endowed Chair in
Geriatric Pharmacology*

Henry J. Mann, Pharm.D.
Professor Emeritus

Susan E. Marino, Ph.D.
Assistant Professor

William S. Oetting, Ph.D.
Professor

Marnie L. Peterson, Ph.D., Pharm.D.
*Associate Professor; Associate Director
of Graduate Studies*

John C. Rotschafer, Pharm.D.
Professor

Shellina Scheiner, Pharm.D.
Assistant Professor

Leo J. Sioris, Pharm.D.
Professor

Debra J. Skaar, Pharm.D.
Associate Professor

Robert J. Straka, Pharm.D.
Professor; Department Head

ADJUNCT FACULTY

Michele Anderson, Ph.D.
Research Assistant Professor

Mary Antonysamy, Ph.D.
Assistant Professor

Andrew Behm, Pharm.D., CGP
Assistant Professor

Greg Beilman, M.D.
Professor

Lisa Coles, Ph.D.
Research Assistant Professor

Kristin Engebretsen, Pharm.D.
Associate Professor

Dean T. Filandrinos, Pharm.D.
Assistant Professor

Mary E. Foss, Pharm.D.
Assistant Professor

John F. Gualtieri, Pharm.D.
Assistant Professor

Nitin Kaila, Ph.D.
Assistant Professor

Reena Kartha, Ph.D.
Research Assistant Professor

Daniel E. Keyler, Pharm.D.
Professor

Frank N. Konstantinides, M.T., M.S.
Professor

Robert Kriel, M.D.
Research Professor

Smita Kshirsagar, Ph.D.
Instructor

Marie D. Kuker, R.Ph.
Assistant Professor

Stephen H. LeMaster, Pharm.D.
Assistant Professor

Len Lichtblau, Ph.D.
Associate Professor

Charles Muscoplat, Ph.D.
Professor

Ramaiah Muthyala, Ph.D.
Associate Professor

Patrick J. Parks, M.D., Ph.D.
Associate Professor

David Parra, Pharm.D.
Associate Professor

Pamela A. Pawloski, Pharm.D.
Assistant Professor

Kelly M. Sioris, Pharm.D.
Assistant Professor

Catherine I. Starner, Pharm.D.
Assistant Professor

Catherine St. Hill, D.V.M., Ph.D.
Associate Professor

John V. St. Peter, Pharm.D.
Associate Professor

Jeanine Utz, Pharm.D.
Assistant Professor

Chester B. Whitley, M.D., Ph.D.
Professor

Rank and appointment as of 12/31/2013.

Research and Administrative Staff

Michele Anderson, Ph.D.	Senior Research Associate, Peterson Lab
Laura Breshears, Ph.D.	Research Associate, Peterson Lab
Marcia Brott	Assistant Scientist, Oetting Lab
Rebecca Brown	Study Coordinator, Jacobson Research Program
Carol Ann Dickinson	Associate Administrator
Sheena Dufresne	Program/Project Specialist
James Fisher	Technical Director, CPAS Laboratory
Kathy Fox	Study Coordinator, Birnbaum Lab
Laurie Baeker Hovde	Coordinator, MTRF Laboratories
Dede Johnston	Associate Administrator
Reena Kartha, Ph.D.	Research Associate, Cloyd Lab
Frank N. Konstantinides, M.T., M.S.	Director, CPAS Laboratory
Kyle LeBlanc	Junior Scientist, Li Lab
Erin McGonagle	Executive Office & Administrative Specialist
Annie Mills	Study Coordinator, Kotlyar Research Program
Usha Mishra	Assistant Scientist, Center for Orphan Drug Research
John O. Rarick	Study Coordinator, Birnbaum Lab
Maryanne Reilly-Spong, Ph.D.	Psychologist, Gross Research Program
Brent Williams	Scientist, CPAS Laboratory

Continuing Graduate Students—Fall 2013

Mariam Ahmed, B.S.	Advisor: Richard C. Brundage, Ph.D., Pharm.D.
Suresh Agarwal, M.S.	Advisor: Richard C. Brundage, Ph.D., Pharm.D.;
	Advisor: James C. Cloyd, Pharm.D.
Neha Bhise, B.Pharm.	Advisor: Jatinder Lamba, Ph.D.
Caroline Churchill, B.S.	Advisor: Carolyn Fairbanks, Ph.D.
Taraswi Mitra Ghosh, M.Sc.	Advisor: Jatinder Lamba, Ph.D.
Aaron Gillman, B.S.	Advisor: Marnie L. Peterson, Ph.D., Pharm.D.
Mary Holmay, R.N.	Advisor: James C. Cloyd, Pharm.D.
David Hottman, B.S.	Advisor: Ling Li, Ph.D.
Krista Johnson, B.S.	Advisor: James C. Cloyd, Pharm.D.
Jia Kang, M.S.	Advisor: Richard C. Brundage, Ph.D., Pharm.D.
Janice Lee, Pharm.D.	Advisor: Angela K. Birnbaum, Ph.D.
Chay Ngee Lim, B.Sc.	Advisor: Angela K. Birnbaum, Ph.D.
Malek Okour, B.S.	Advisor: Richard C. Brundage, Ph.D., Pharm.D.
Youssef Roman, Pharm.D.	Advisor: Robert J. Straka, Pharm.D.
Kinjal Sanghavi, B.Pharm.	Advisor: Vishal Lamba, Ph.D.
Harrison Tam, B.S.	Advisor: LAurelle A. Johnson, Ph.D.
Jie Zhou, M.S.	Advisor: James C. Cloyd, Pharm.D.

New Graduate Students—Fall 2013

Ali Alhadab, Pharm.D.	Advisor: Marnie L. Peterson, Ph.D., Pharm.D.
Cristina Peterson, B.S.	Advisor: Carolyn Fairbanks, Ph.D.

New and Continuing Post-Docs, Fellows, and Residents

Laura Breshears, Ph.D.	Advisor: Marnie L. Peterson, Ph.D., Pharm.D.
Lata Chauhan, Ph.D.	Advisor: Jatinder Lamba, Ph.D.
Shaowu Cheng, Ph.D.	Advisor: Ling Li, Ph.D.
Darcy Flora, Ph.D.	Advisor: Richard C. Brundage, Ph.D., Pharm.D.
Patrick Sorgen, Ph.D.	Advisor: James C. Cloyd, Pharm.D.

ECP Department faculty conduct groundbreaking research in areas such as oncology, transplantation, infectious diseases, pharmacogenomics, orphan drugs, cardiovascular diseases, Alzheimer's, and critical care.

RESEARCH

Groundbreaking and critical research is conducted in the Department of Experimental and Clinical Pharmacology. Faculty research programs focus on oncology, transplantation, infectious diseases, genomics, geriatrics, critical care, neuroscience, cardiovascular diseases, pediatrics, integrative therapies and outcomes, and psychiatry. ECP is home to the Lawrence C. Weaver Endowed Chair in Orphan Drug Development and the VFW Endowed Chair in Geriatric Pharmacotherapy. In addition, ECP's state-of-the-art, CLIA-certified Clinical Pharmacology Analytical Services Laboratory has provided an important research resource to both University researchers and external customers for ten years.

Our 23 regular faculty members routinely present important research findings at national and international conferences, lecture and collaborate across the country, serve as reviewers and editorial board members of international journals, hold leadership positions in national organizations, and serve on National Institutes of Health and other granting agencies' review committees.

In 2013:

- New grants received by ECP faculty = 19
- Peer-reviewed articles published by ECP faculty = 49
- Books and chapters published by ECP faculty = 7
- Department expenditures on sponsored projects (exclusive of salaries/fringe) = \$1,512,919
- Department salaries/fringe offset by sponsored projects in 2013 = \$2,037,071
- Percentage of ECP faculty salaries generated by sponsored projects in FY 2013 (July 1, 2012 to June 30, 2013) = 21.3%

Research Centers within ECP

- Center for Forecasting Drug Response
- Center for Orphan Drug Research (Dr. Jim Cloyd)
- Center for Clinical and Cognitive Neuropharmacology (Dr. Susan Marino)
- Center for Excellence in Critical Care (Dr. Greg Beilman)
- Pathway-Driven Pharmacogenomics University of Minnesota Alliance (Dr. Jatinder Lamba)



New Sponsored Projects by ECP Faculty in 2013

Faculty	Project Description	Sponsor
Richard C. Brundage (Co-I)	Testing the Penetration of Moxifloxacin into Chinchilla	Alcon Laboratories, Inc.
James C. Cloyd (Co-I), Lisa Coles (Co-I)	Prevention of Baclofen Withdrawal Syndrome: Two-Way Crossover Study	Medtronic, Inc.
James C. Cloyd (Co-I), Lisa Coles (Co-I)	Identifying New Therapies for Infantile Spasms	Cure Foundation/Department of Defense
James C. Cloyd (PI)	Pharmacotherapy of Inherited Metabolic Disease Pharm.D. Fellowship	Genzyme Corporation
James C. Cloyd (PI), Lisa Coles (Co-I)	Differential Pharmacological Effect of Ezogabine on Canine EEG	GlaxoSmithKline
James C. Cloyd (PI)	Analysis of Intra-subject Variability in Plasma Topiramate Concentrations following Administration of Extended Release Topiramate	Upsher-Smith Laboratories, Inc.

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New Sponsored Projects by ECP Faculty in 2013, continued

Faculty	Project Description	Sponsor
Esam E. El-Fakahany (Co-I)	Leveraging Best Practices in Mentoring from the Collective Experience of CNPCs	NIH National Institute on Minority Health and Health Disparities
Michael Kotlyar (PI)	GRAND 2012: Use of Medicinal Nicotine for Preventing Cue-Induced Craving and Withdrawal Symptoms	Pfizer, Inc.
Michael Kotlyar (PI)	Smoker Response to Banning of Menthol-Flavored Cigarettes	Clearway MN
Robert Kriel (PI), James C. Cloyd (Co-I), Lisa Coles (Co-I)	Two-Way Crossover Study of Oral and Intravenous Baclofen	Paralyzed Veterans of America
Vishal Lamba (Co-I)	Cannabinoid-Based Therapy and Approaches to Quantify Pain in Sickle Cell Disease	NIH National Heart, Lung, and Blood Institute
Ling Li (PI)	ApoJ/Clusterin Peptide as a Novel Therapeutic Agent for Alzheimer's Disease	Alzheimer's Drug Discovery Foundation
Ling Li (Co-I)	Training Grant: Functional Proteomics of Aging	NIH National Institute on Aging
Susan E. Marino (PI), Angela K. Birnbaum (Co-I), Pamala A. Jacobson (Co-I)	Cognitive and Motor Effects of Treatment with a Calcineurin Inhibitor (Tacrolimus) versus Belatacept in Kidney Transplant Patients	Bristol-Myers Squibb Company

New Intramural Projects by ECP Faculty in 2013

Faculty	Project Description	Sponsor
Jeannine Conway (PI)	Pharmacist and Nurse Clinical Decision-Making: An Initial Exploration of Shared Decision-Making Processes	U of M Grant-in-Aid of Research, Artistry and Scholarship
Jatinder K. Lamba (PI)	Pharmacogenomics of Ara-C in Pediatric Acute Myeloid Leukemia Patients	U of M Grant-in-Aid of Research, Artistry and Scholarship
Ling Li (PI)	Purchase of Tabletop Ultracentrifuge	U of M Grant-in-Aid of Research, Artistry and Scholarship
Ling Li (PI)	Therapeutic Potential of a Novel Neuroprotective Agent for Alzheimer's Disease	Engebretson/Bigley Drug Design & Development Grant
Marnie L. Peterson (PI)	Alpha Toxin: Role in Biofilm Formation by MRSA Wound Isolates and Therapeutic Target	U of M CTSI-Ed R-to-R Scholars Program Grant

Ongoing Sponsored Projects by ECP Faculty in 2013

Faculty	Project Description	Sponsor
Angela K. Birnbaum (PI)	Maternal Outcomes and Neurodevelopmental Effects of Antiepileptic Drugs – Pharmacokinetics Laboratory Core	NIH National Institute of Neurological Disorders and Stroke
Angela K. Birnbaum (PI), Ilo E. Leppik (Co-I), Susan E. Marino (Co-I)	Clinical Impact of Unstable AED Levels in Elderly Nursing Home Epilepsy Patients	NIH National Institute on Aging

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Ongoing Sponsored Projects by ECP Faculty in 2013, continued

Faculty	Project Description	Sponsor
Angela K. Birnbaum (Co-I)	Multivalent Vaccine for Opiate Addiction	NIH National Institute on Drug Abuse
Angela K. Birnbaum (Co-I)	Preclinical Studies of a Heroin/Morphine Vaccine for Opiate Addiction	NIH National Institute on Drug Abuse
Angela K. Birnbaum (Co-PI), Jatinder Lamba (Co-PI)	Pharmacogenomics and Pharmacokinetics of Lamotrigine in Early Pregnancy	Epilepsy Foundation of America, Inc.
Angela K. Birnbaum (PI)	Pharsight–University of Minnesota Pharmacometrics Collaboration	Pharsight Corporation
Richard C. Brundage (PI)	Pharmacogenetics and Drug Interactions	NIH National Institute of General Medical Sciences
Richard C. Brundage (Co-I)	University of Minnesota Clinical and Translational Science Institute	NIH National Center for Research Resources
Richard C. Brundage (Co-I), Ilo E. Leppik (Co-I)	Genotype-Dependent Drug Interactions	NIH
Richard C. Brundage (PI)	Novartis Pharmacometrics Traineeship	Novartis Pharma AG
Richard C. Brundage (PI)	Pfizer Pharmacometrics Traineeship	Pfizer, Inc.
James C. Cloyd (PI)	Clinical Pharmacotherapy and Pharmacogenetics of Inherited Metabolic Diseases	Genzyme Corporation
James C. Cloyd (Co-I), Reena Kartha (Co-I)	Phase II Clinical Trial to Evaluate the Benefits of Post-Conditioning in STEMI	NIH National Heart, Lung, and Blood Institute

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Ongoing Sponsored Projects by ECP Faculty in 2013, continued

Faculty	Project Description	Sponsor
James C. Cloyd (Co-I), Lisa Coles (Co-I)	Neurophysiologically Based Responsive Pharmacotherapy for Epilepsy	NIH
James C. Cloyd (PI)	The Human Epilepsy Project	Epilepsy Study Consortium
James C. Cloyd (PI)	Lysosomal Disease Network	NIH National Institute of Neurological Disorders and Stroke
Jeannine M. Conway (PI)	A Pharmacy Coordinated Program to Enhance Medication Use in Chronic Cardiovascular Disease in a Rural Minnesota Community	MN Department of Health
Cynthia R. Gross (Co-I)	Studies of Organ Transplantation in Animals and Man	NIH National Institute of Diabetes and Digestive and Kidney Diseases
Pamala A. Jacobson (Co-I), Mark N. Kirstein (Co-I)	Cancer Center Support Grant	NIH National Cancer Institute
Pamala A. Jacobson (Co-I), William S. Oetting (Co-I)	Genomics of Kidney Transplantation	NIH National Institute of Allergy and Infectious Diseases
Mark N. Kirstein (PI)	Evaluation of Antitumor Efficacy for Imprime PGG + Monoclonal Antibody Combination in Pancreatic Tumor Mouse Model	Biothera
Mark N. Kirstein (PI)	Vitamin D ₃ Effects on Musculoskeletal Symptoms with Use of Aromatase Inhibitors	Park Nicollet Institute

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Ongoing Sponsored Projects by ECP Faculty in 2013, continued

Faculty	Project Description	Sponsor
Michael Kotlyar (PI)	Medicinal Nicotine for Preventing Stress-Induced Craving and Withdrawal Symptoms	NIH National Institute on Drug Abuse
Jatinder Lamba (PI)	Impact of Genetic Variation on Response to GO Therapy in COG-AML Clinical Trials	NIH National Cancer Institute
Jatinder Lamba (PI)	Pharmacogenetics of Ara-C Metabolic Pathway	NIH National Cancer Institute
Vishal Lamba (Co-I)	Genetic and Time-Frequency Aspects of Neural Phenotypes in Schizophrenia	US Department of Veterans Affairs
Ilo E. Leppik (PI), James C. Cloyd (Co-PI)	Canine Status Epilepticus: A Translational Platform for Human Therapeutics Trials	NIH National Institute of Neurological Disorders and Stroke
Ilo E. Leppik (PI)	An Open-Label Safety Study of USL261 in the Outpatient Treatment of Subjects with Seizure Clusters	PharmaNet, Inc.
Ilo E. Leppik (PI)	A Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of Intranasal Midazolam (USL261) in the Outpatient Treatment of Subjects with Seizure Clusters	PharmaNet, Inc.
Ling Li (PI)	A Novel Role of ApoA-I in Alzheimer's Disease	BrightFocus Foundation
Ling Li (PI)	Protective Mechanisms of Statins in Alzheimer's Disease	NIH National Institute on Aging
Susan E. Marino (PI), Angela K. Birnbaum (Co-I), Ilo E. Leppik (Co-I)	Characterizing and Predicting Drug Effects on Cognition	NIH National Institute of Neurological Disorders and Stroke

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Ongoing Sponsored Projects by ECP Faculty in 2013, continued

Faculty	Project Description	Sponsor
Susan E. Marino (PI)	Professional Fighters Brain Health Study	The Cleveland Clinic
William S. Oetting (Co-I)	Twin Study of ADHD, CD and Substance Abuse	NIH National Institute on Drug Abuse
William S. Oetting (Co-I)	Statistical Model Building for High Dimensional Biomedical Data	NIH National Institute of General Medical Sciences
William S. Oetting (Co-I)	Substance Abuse & Behavioral Disinhibition: Integrating Genes & Environment	NIH National Institute on Drug Abuse
Marnie L. Peterson (Co-I), William S. Oetting (Co-I)	Immunological Factors and Risk of Vulvodynia	NIH National Institute of Child Health and Human Development
Marnie L. Peterson (PI)	Mucosal Models for Skin and Wound Infections	3M
Marnie L. Peterson (PI)	Mucosal Models of Infection for Antisepsis	3M
Marnie L. Peterson (PI)	Biomarker Analysis of Non-Healing Wounds as a Function of Treatment	3M
Marnie L. Peterson (Co-I)	Cardiotoxicity of Streptococcal Pyrogenic Exotoxins	NIH National Institute of Allergy and Infectious Diseases
Marnie L. Peterson (PI)	Staphylococcal Superantigen Interactions with Vaginal Epithelium	NIH National Institute of Allergy and Infectious Diseases
Shellina R. Scheiner (Co-I)	Minnesota Area Geriatric Education Center	US Department of Health and Human Services HRSA

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Ongoing Sponsored Projects by ECP Faculty in 2013, continued

Faculty	Project Description	Sponsor
Debra J. Skaar (Co-I)	Testing the Feasibility of Patient-Controlled Sedation in Ventilated ICU Patients	NIH National Institute of Nursing
Jeanine Utz (PI)	Placebo Controlled Trial Evaluating Gabapentin for the Treatment of Small Fiber Neuropathic Pain in Patients with Fabry Disease	Genzyme Corporation

Ongoing Intramural Projects by ECP Faculty in 2013

Faculty	Project Description	Sponsor
James C. Cloyd (Co-PI)	Diazepam Prodrugs for the Treatment of Seizure Emergencies	AHC Faculty Development Grant
Reena Kartha (Co-I)	Determination of Endogenous Levels of Nitric Oxide and Hydrogen Sulfide in Patients with Obstructive Sleep Apnea	University of Minnesota Foundation
Mark N. Kirstein (Co-I)	Pilot Analysis of Unbound Sorafenib: Relevance to Efficacy and Toxicity in a Phase I Trial and to In-vitro Cytotoxicity	University of Minnesota Foundation
Jatinder Lamba (PI)	Generation of Genetically Diverse Liver Cultures from Skin-Derived iPS Libraries	University of Minnesota Foundation
Vishal Lamba (PI)	Use of HapMap Lymphoblastoid Cell Lines to Identify Pharmacogenetic Predictors of Mycophenolate Tox.	U of M Grant-in-Aid of Research, Artistry and Scholarship
Marnie L. Peterson (PI)	Development of a Biotherapeutic for Prophylaxis and Treatment of <i>S. aureus</i> Disease	Engbretson/Bighley Drug Design & Development Grant
Robert J. Straka (PI)	Pharmacogenomic Markers of Lipid Response to Fenofibrate in a Hispanic Population	UMN Institute of Human Genetics

Published Articles by ECP Faculty in 2013

Puranik YG, **Birnbaum AK**, **Marino SE**, Ahmed G, **Cloyd JC**, Rimmel RP, **Leppik IE**, **Lamba JK**. Association of carbamazepine major metabolism and transport pathway gene polymorphisms and pharmacokinetics in patients with epilepsy. *Pharmacogenomics*. 2013 Jan;14(1):35-45. PMID: 23252947

Raleigh MD, Pravetoni M, Harris AC, **Birnbaum AK**, Pentel PR. Selective effects of a morphine conjugate vaccine on heroin and metabolite distribution and heroin-induced behaviors in rats. *J Pharmacol Exp Ther*. 2013 Feb;344(2):397-406. Epub 2012 Dec 7. PMID: 23220743

Jones JM, Raleigh MD, Pentel PR, Harmon TM, Keyler DE, Rimmel RP, **Birnbaum AK**. Stability of heroin, 6-monoacetylmorphine, and morphine in biological samples and validation of an LC-MS assay for delayed analyses of pharmacokinetic samples in rats. *J Pharm Biomed Anal*. 2013 Feb 23;74:291-7. Epub 2012 Nov 15. PMID: 23245263 PMCID: PMC3789381

Munn MS, Sibley S, **Brundage RC**, Ismail B, Earthman CP. Angiotensin-converting enzyme inhibitory effects of dairy- and soy-derived peptides in pre-hypertensive overweight men and women. *Functional Foods in Health and Disease*. 2013; 3(1):37-47.

Ivaturi V, Kriel R, **Brundage R**, Loewen G, Mansbach H, **Cloyd J**. Bioavailability of intranasal vs. rectal diazepam. *Epilepsy Res*. 2013 Feb;103(2-3):254-61. Epub 2012 Sep 13. PMID: 22981338

Milán Segovia RC, Domínguez Ramírez AM, Jung Cook H, Magaña Aquino M, Vigna Pérez M, **Brundage RC**, Romano Moreno S. Population pharmacokinetics of rifampicin in Mexican patients with tuberculosis. *J Clin Pharm Ther*. 2013 Feb;38(1):56-61. Epub 2012 Nov 20. PMID: 23167603

Ahmed GF, **Brundage RC**, **Marino SE**, **Cloyd JC**, **Leppik IE**, Pennell PB, Ramsay RE, **Birnbaum AK**. Population pharmacokinetics of unbound and total drug concentrations following intravenously administered carbamazepine in elderly and younger adult patients with epilepsy. *J Clin Pharmacol*. 2013 Mar;53(3):276-84. Epub 2013 Feb 13. PMID: 23408495

Agarwal SK, Kriel RL, **Brundage RC**, Ivaturi VD, **Cloyd JC**. A pilot study assessing the bioavailability and pharmacokinetics of diazepam after intranasal and intravenous administration in healthy volunteers. *Epilepsy Res*. 2013 Aug;105(3):362-7. Epub 2013 Apr 2. PMID: 23561287

Clark AM, Mondick JT, **Cloyd JC**, Zuppa AF, Raol YH, Clancy RR. Plasma topiramate concentrations resulting from doses associated with neuroprotection against white matter injury and stroke in two strains of rat pups. *Pediatr Res*. 2013 Mar;73(3):317-24. Epub 2012 Dec 19.

Holmay MJ, Terpstra M, Coles LD, Mishra U, Ahlskog M, Öz G, **Cloyd JC**, Tuite PJ. N-acetylcysteine boosts brain and blood glutathione in Gaucher and Parkinson diseases. *Clin Neuropharmacol*. 2013 Jul-Aug;36(4):103-6. PMID: 23860343

Bleck T, Cock H, Chamberlain J, **Cloyd J**, Connor J, Elm J, Fountain N, Jones E, Lowenstein D, Shinnar S, Silbergleit R, Treiman D, Trinka E, Kapur J. The established status epilepticus trial 2013. *Epilepsia*. 2013 Sep;54 Suppl 6:89-92. PMID: 24001084

Coles LD, Patterson EE, Sheffield WD, Mavoori J, Higgins J, Michael B, Leyde K, **Cloyd JC**, Litt B, Vite C, Worrell GA. Feasibility study of a caregiver seizure alert system in canine epilepsy. *Epilepsy Res*. 2013 Oct;106(3):456-60. Epub 2013 Aug 18. PMID: 23962794 PMCID: PMC3903427

McNamara A, Janke KK, **Conway J**, Schweiss S. Student self-ratings of skill acquisition from a clinical controversy debate in a third year pharmaceutical care lab. *Innovations in Pharmacy*. 2013 Dec;4(4):130.

Published Articles by ECP Faculty in 2013, continued

- Janičková H, Rudajev V, Zimčík P, Jakubík J, Tanila H, **El-Fakahany EE**, Doležal V. Uncoupling of M₁ muscarinic receptor/G-protein interaction by amyloid β (1-42). *Neuropharmacology*. 2013 Apr;67:272-83. Epub 2012 Nov 30. PMID: 23206502
- Nolan VG, Gapstur R, **Gross CR**, Desain LA, Neglia JP, Gajjar A, Klosky JL, Merchant TE, Stovall M, Ness KK. Sleep disturbances in adult survivors of childhood brain tumors. *Qual Life Res*. 2013 May;22(4):781-9. Epub 2012 Jun 6. PMID: 22669471
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With more than two dozen faculty and a dedicated administrative and research staff, ECP trains professional, graduate, and post-graduate students of the highest caliber while advancing a widely respected research program.

TEACHING

The College of Pharmacy consistently ranks among the top three pharmacy schools in the nation. In 2013, ECP faculty provided 2,104.5 hours of didactic education to 167 pharmacy students per class year, as well as students in dentistry, nursing, public health, geriatrics, and genetics. Instruction to pharmacy students included experiential education in acute care, geriatric patient care, pediatric infectious disease, and clinical toxicology. It also included teaching and directing in the pharmacotherapy series and the pharmaceutical care skills course sequence, and teaching other elective courses. In addition, ECP members participated in journal clubs throughout the University in their areas of interest and with research collaborators.

In 2013, ECP faculty mentored:

- 15 students on special research projects funded under CTSI/CHE, Melendy Scholarships, or Undergraduate Research Opportunities Program
- 11 undergraduate students
- 14 professional students
- 13 graduate students in non-ECP programs
- 13 post-doctoral fellows or residents

In 2013, ECP faculty:

- offered clerkships or experiential instruction to 79 students
- served as advisors or readers on thesis projects to 107 pharmacy students

Innovations in Teaching

Angela Birnbaum, Pamala Jacobson, and Marnie Peterson developed the new Research Emphasis for the pharmacy program, approved by the College Assembly in 2013. The first applicants were received in Fall 2013. Birnbaum and Peterson then worked with **Carol Ann Dickinson** and **Catherine St. Hill** to create “Introduction in Pharmacy Research” (PHAR 6206), which is required for the Research Emphasis.

Richard Brundage presented two workshops on population pharmacokinetics at Mayo Hospital in Rochester. He also gave several lectures via the web for the University of Manchester on the impact of LLOQ censoring in NONMEM, on correlations between dose and clearance in therapeutic drug monitoring settings, and on Mixture Modeling in NONMEM.



Jeannine Conway worked with residents and P4 students to develop an immunization refresher lab, a drug information lab, and an herbal product lab. She was also selected Fall 2013 Teacher of the Semester (Class of 2015, Twin Cities) and 2013 Teacher of the Graduating Class (Twin Cities).

Esam El-Fakahany was co-director of the College of Pharmacy’s Workshop Series on Writing Successful Fellowship Applications; he also moderated numerous workshops for graduate students and fellows on behalf of CTSI, the Center for Teaching and Learning, and the Graduate School.

Pamala Jacobson was awarded the 2013 Graduate and Professional Student Association Outstanding Advisor Award. The award, which is University-wide, recognizes advisors who go out of their way to create a positive learning environment. Jacobson was one of only five recipients; nominations come directly from students.

Pamala Jacobson delivered a ten-day course in pharmacogenomics to clinical pharmacists and interns at Singapore General Hospital and gave the keynote presentation at the 23rd Singapore Pharmacy Congress.

Robert Straka presented on cardiovascular topics for the hospital course, and spoke at the Cardiovascular Research Institute of the Yoo Loo Lin School of Medicine at the National University of Singapore.

Marnie Peterson developed a international collaborative Ph.D. student research program with the University of Birmingham and the Queen Elizabeth Hospital Birmingham in the United Kingdom.

John Rotschafer was named Spring 2013 Teacher of the Semester (Class of 2014, Twin Cities). He also developed the antibiotics curriculum for the Dental School’s “Dental Pharmacology” course (DDS 6215).



The hours of service by ECP faculty and staff enhance the standing of the College in the profession and in the community, and are an opportunity to develop collaborations nationally and internationally.

SERVICE

In addition to their college teaching and research, many ECP faculty discover opportunities for service both within the University and with outside organizations and companies. The immeasurable hours they spend offering expertise and guidance are a way to give back to the community, peers and students, and the field.

Faculty cited service to 22 national committees in 2013, including NIH study section committees, abstract review committees, and program planning committees for national organizations. Faculty served on 35 University and AHC committees including the Faculty Senate, the Graduate Education Council, search committees, scientific advisory groups, and others. They also had a total of 81 service commitments to committees within the College of Pharmacy and 26 within ECP. Faculty members had appointments on boards of directors or professional advisory boards of research organizations; others had appointments on standards and education committees with health providers in Minnesota such as HealthPartners, Regions, and Fairview.

In 2013, faculty served on the editorial boards of the *Austin Journal of Endocrinology and Diabetes*, *BMC Nephrology*, *Epilepsia*, *Frontiers in Cellular and Infection Microbiology*, *Frontiers in Neurodegenerative Diseases*, *Frontiers in Pharmacogenetics and Pharmacogenomics*, *Human Mutation*, *International Scholarly Research Network – Pharmacology*, *Journal of Geriatrics and Palliative Care*, *Journal of Pharmacology and Drug Metabolism*, *Pharmacogenomics*, *Pharmacotherapy*, and *Scientific World Journal – Genetics*. In addition, they served as manuscript reviewers for 57 journals; as proposal reviewers for 11 funding bodies; and as reviewers of faculty promotion documents for institutions across the country and around the world.

Highlights in Service

Angela Birnbaum worked with Pharsight to host a special, three-day training workshop in Phoenix WinNonLin software for ECP, Medicinal Chemistry, and Pharmaceutics graduate students and post-docs, as well as eight participants from outside the University. Birnbaum was able to secure the University registrations for free or at cost. She is working with the company to plan a similar NLME workshop for 2014.



Jim Cloyd and members of the Center for Orphan Drug Research helped plan and facilitate the Rare Diseases Day at Nickelodeon Universe at Mall of America, where 150 kids with rare diseases and their families were able to enjoy the rides and activities for free while park staff made sure their unique accessibility and safety needs were met.



Jeannine Conway served as the pharmacist for Camp Oz, a summer camping experience organized by the Epilepsy Foundation of Minnesota for kids with seizures.

Cynthia Gross was a faculty participant in the 2013 Rein in Sarcoma Foundation Mini Medical School, held at the University of Minnesota. Within the day's focus on sarcoma research that is ongoing at the U, she

spoke on the topic of training therapy dogs.

William Oetting was named an Honorary Member of the Pan American Society for Pigment Cell Research, which bestowed the recognition "for his exceptional and lasting service."

Marnie Peterson gave a lecture on research and drug discovery to students from Trinity School at River Ridge, a junior high and high school in Eagan.

Debra Skaar served as the faculty liaison to the University of Minnesota's student chapter of AACP.



The Graduate Program provides individualized hands-on learning experiences to those who will become tomorrow's leaders in experimental and clinical pharmacology research and teaching.

GRADUATE PROGRAM

The ECP Graduate Program is an innovative, interdisciplinary program that trains students to conduct research encompassing methodology from basic and clinical pharmacology perspectives. It was designed specifically for students interested in clinical research with the goal to advance the science of human pharmacology and therapeutics to improve the safe, effective, and economical use of drugs by patients. Students study such topics as experimental pharmacotherapy, drug metabolism, infectious disease, pharmacometrics, and pharmacogenomics. Graduates are prepared for distinguished careers in clinical research.

ECP celebrated the graduation of 3 students in 2013 (bringing the total number of program graduates to 37), and had a total of 19 new and continuing students in the program as of Fall 2013.

New Students—Fall 2013

The department admitted two new students in Fall 2013:

Ali Alhadab, Pharm.D.	Advisor: Marnie L. Peterson, Ph.D., Pharm.D.
Cristina Peterson, B.S.	Advisor: Carolyn Fairbanks, Ph.D.

New Ph.D. Candidates in 2013

These students became Ph.D. candidates by passing their oral preliminary exams:

Suresh Agarwal, M.S.
Neha Bhise, B.Pharm.
Aaron Gillman, B.S.
Harrison Tam, B.S.

ECP Ph.D. Graduates in 2013

Graduate	Thesis Title	Advisor	Current Position
Gavin Bart, M.D., Ph.D.	Methadone population pharmacokinetics: Toward understanding the dose-response relationship in the treatment of opiate addiction	Richard C. Brundage, Ph.D., Pharm.D.	Division Director of Addictive Medicine, Hennepin County Medical Center
Manoj Chiney, M.Pharm., Ph.D.	Effect of obesity on hepatic drug metabolism	LAurelle A. Johnson, Ph.D.	Research Investigator, Bristol-Myers Squibb
Jia Kang, M.S., Ph.D.	Pharmacometric analyses of drug exposure and response data	Richard C. Brundage, Ph.D., Pharm.D.	Research Scientist – Pharmacometrics, Metrum Research Group LLC

Presentations by Graduate Students or Post-Docs in 2013

Agarwal S. Model-based approach to designing efficient and informative trials. Presented at: Center for Orphan Drug Research Seminar, College of Pharmacy, University of Minnesota; 2013 Apr 4; Minneapolis, MN.

Agarwal S. Placebo response in medicine: minimize, maximize or personalize? Presented at: Center for Orphan Drug Research Seminar, College of Pharmacy, University of Minnesota; 2013 Dec 12; Minneapolis, MN.

Ahmed M. Application of deconvolution to the analysis of intranasal diazepam data. Presented at: Department of Experimental and Clinical Pharmacology Weekly Seminar, College of Pharmacy, University of Minnesota; 2013 Jan 30; Minneapolis MN.

Bhise N. Development of resistance to nucleoside analogs. Presented at: Department of Experimental and Clinical Pharmacology Weekly Seminar, College of Pharmacy, University of Minnesota; 2013 Nov 6; Minneapolis, MN.

Churchill C. AAV gene therapy to the choroid plexus for chronic pain. Presented at: The Neurovascular Unit/Blood-Brain Barrier Mini-Symposium, University of Minnesota; 2013 Oct; Duluth, MN.

Churchill C. AAV-agmatine decarboxylase gene therapy and agmatine's role in NMDA Receptor Signaling. Presented at: PharmacoNeuroImmunology Research-in-Progress Symposium, University of Minnesota; 2013 Oct; St. Paul, MN.

Mitra Ghosh T. Pharmacogenomic of chemotherapeutic agents-platinating agents and taxanes/taxol. Presented at: Department of Experimental and Clinical Pharmacology Weekly Seminar, College of Pharmacy, University of Minnesota; 2013 Sep 11; Minneapolis, MN.

Presentations by Graduate Students or Post-Docs in 2013, continued

Gillman A. Could inhibition of local inflammation aid in treatment of staphylococcus aureus- induced Toxic Shock Syndrome? Presented at: Department of Experimental and Clinical Pharmacology Weekly Seminar, College of Pharmacy, University of Minnesota; 2013 Apr 17; Minneapolis, MN.

Hottman D. Impact of human cholesteryl ester transfer protein on cognitive function and neuropathology in a mouse model of Alzheimer's disease. Presented at: Department of Experimental and Clinical Pharmacology Weekly Seminar, College of Pharmacy, University of Minnesota; 2013 Nov 13; Minneapolis, MN.

Johnson K. Medical countermeasures against chemical threats. Presented at: Department of Experimental and Clinical Pharmacology Weekly Seminar, College of Pharmacy, University of Minnesota; 2013 Oct 16; Minneapolis, MN.

Laramy J. Levetiracetam in pregnant women. Presented at: Department of Experimental and Clinical Pharmacology Weekly Seminar, College of Pharmacy, University of Minnesota; 2013 Feb 13; Minneapolis, MN.

Ngee Lim C. Quantitative approach to investigating effects of anti-epileptic drugs on cognition. Presented at: Department of Experimental and Clinical Pharmacology Weekly Seminar, College of Pharmacy, University of Minnesota; 2013 Nov 20; Minneapolis, MN.

Okour M. Introduction to population pharmacometrics. Presented at: Department of Experimental and Clinical Pharmacology Weekly Seminar, College of Pharmacy, University of Minnesota; 2013 Sep 18; Minneapolis, MN.

Roman Y. Role of genetics on hyperuricemia in Hmong. Presented at: Department of Experimental and Clinical Pharmacology Weekly Seminar, College of Pharmacy, University of Minnesota; 2013 Oct 23; Minneapolis, MN.

Sanghavi K. Pharmacogenomics of mycophenolic acid. Presented at: Department of Experimental and Clinical Pharmacology Weekly Seminar, College of Pharmacy, University of Minnesota; 2013 Feb 20; Minneapolis, MN.

Zhou J. N-acetylcysteine in childhood cerebral adrenoleukodystrophy: new insights into its pharmacology. Presented at: Department of Experimental and Clinical Pharmacology Weekly Seminar, College of Pharmacy, University of Minnesota; 2013 Mar 13; Minneapolis MN.

Zhou J. Improving pre-clinical research through rigorous study design and transparent reporting. Presented at: Center for Orphan Drug Research Seminar, College of Pharmacy, University of Minnesota; 2013 Oct 17; Minneapolis, MN.

Abstracts—Posters and Presentations by Graduate Students or Post-Docs in 2013

Laramy JK, Leppik IE, Kistner BM, Rarick JO, McCarthy TC, Birnbaum AK. Antiepilepsy drugs and comedications in elderly nursing home patients with epilepsy. Presented at: American Epilepsy Society Annual Meeting; 2013 December; Washington, DC.

Ngee Lim C, Prasittisopin B, Ramsay RE, Collins JF, Leppik IE, Birnbaum AK. Variability of lamotrigine and carbamazepine concentrations in elderly community dwelling patients. Poster presented at: American Epilepsy Society Annual Meeting; 2013 December; Washington, DC.

Abstracts—Posters and Presentations by Graduate Students or Post-Docs in 2013, continued

Mitra Ghosh T, Feldberg TJ, Lamba JK. Screening of in vitro cytotoxicity of nucleoside analogs in HapMap cell lines to identify predictive markers of drug sensitivity. Poster presented at: Rho Chi Research Symposium. University of Minnesota; 2013 April 4; Minneapolis, MN. [Winner, Best Poster Award]

Mitra AK, **Mitra Ghosh T**, Feldberg TJ, Pounds S, Cao X, Lamba JK. SNPs in ribonucleotide reductase genes RRM1 and RRM2 are associated with mRNA expression and response to nucleoside analogs-based chemotherapy. Poster presented at: American Society for Clinical Pharmacology and Therapeutics Annual meeting; 2013 March 5-9; Indianapolis, IN.

Lamba JK, Feldberg TJ, **Mitra Ghosh T**, **Bhise N**, Fridley B. Genome-wide association analysis identified genetic markers associated with triptolide cellular sensitivity using HapMap LCLs as model system. Poster presented at: American Association for Cancer Research Annual Meeting; 2013 April 6-10; Washington, DC.

Chauhan L, Feldberg TJ, **Mitra Ghosh T**, **Bhise N**, Fridley B, Lamba JK. Genome-wide association analysis identified genetic markers associated with triptolide cellular sensitivity using HapMap LCLs as model system. Poster presented at: Rho Chi Research Symposium. University of Minnesota; 2013 April 4; Minneapolis, MN.

Chauhan L, Fridley B, Feldberg TJ, **Mitra Ghosh T**, **Bhise N**, Lamba J. Cflar genetic variant resulting in alternate splicing determines isoform specific production of H-Cflar protein and is predictive of cellular cytotoxicity of triptolide in HapMap lymphoblast and AML cell lines. Poster presented at: American Society of Hematology Annual Meeting and Exposition; 2013 December 7-10; New Orleans, LA.

Okour M, Brundage R, Jacobson P. Correlations between biomarkers and therapeutic outcomes: application to mycophenolic acid and kidney transplantation. Poster presented at: CTSI Poster Session & Reception; 2013 October 1; Minneapolis, MN. [Winner, Best Poster – Advanced Research Program]

Roman Y, Xiong J, Culhane-Pera K, Straka R. Analysis of single nucleotide polymorphisms (SNPs) in Hmong population and hyperuricemia. Poster presented at: CTSI Poster Session & Reception; 2013 October 1; Minneapolis, MN.

Tam H, Subramanian M, Tracy T. Substrate dependent metabolism by cytochrome P450 2C9.1, .2, .3, .5, .8, .11, and .13 variants expressed in Supersomes™. Poster presented at: 18th International Conference on Cytochrome P450; 2013 June 18-22; Seattle, WA.

Published Articles by Graduate Students or Post-Docs in 2013

Agarwal SK, Kriel RL, Brundage RC, Ivaturi VD, Cloyd JC. A pilot study assessing the bioavailability and pharmacokinetics of diazepam after intranasal and intravenous administration in healthy volunteers. *Epilepsy Res.* 2013 Aug;105(3):362-7. PMID: 23561287

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Cheng S, Cao D, **Hottman DA**, Yuan L, Bergo MO, Li L. Farnesyltransferase haploinsufficiency reduces neuropathology and rescues cognitive function in a mouse model of Alzheimer disease. *J Biol Chem.* 2013 Dec 13;288(50):35952-60. Epub 2013 Oct 17. PMID: 24136196



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