What’s Inside:
Three New Faculty Join ECP p.3
K-Award for HIV/AIDS Prevention Research p.6
Alumni Spotlight p.7
Dear Friends,

As we near the end of the academic year in ECP, we reflect on the significant accomplishments of the last eight months and begin planning for the summer and academic year to follow.

In the last year, ECP has been fortunate to welcome three new outstanding faculty—Drs. Mahmoud Al-Kofahi, Stephanie Huang, and Elizabeth Hirsch. Each represent excellent additions to our existing faculty expertise in pharmaceutics, infectious disease, and pharmacogenomics. In this past year, we also witnessed the bittersweet retirements of faculty member Dr. Cynthia Gross and Graduate Program Administrator Mary Moreno Lien. Graduate students Ali Al-Hadab, David Hottman, Christina Peterson, and Youssef Roman successfully defended their theses and moved on to the next stages of their promising careers.

ECP continues to seek out communities and collaborations that foster innovation both at home and abroad. This fall, we continued to lay the groundwork for a promising bilateral partnership with China Pharmaceutical University in Nanjing, China, and we look forward to hosting our second biennial Precision Medicine Conference on June 22, 2018, right here at the U of M.

Though the faces change, you will see in the following pages that our faculty, staff, students, and alumni continue to garner recognition at the highest levels of our discipline for their work as researchers, clinicians, and engaged members of their scientific and scholarly communities. We delight in their achievements, and in the continued success of all our alumni and friends.

I wish our faculty, staff, students, and academic colleagues the best of luck in the remainder of the semester, and look forward with you all to warmer days ahead.

Sincerely,

Robert J. Straka, Pharm.D.
Department Head
Dr. Al-Kofahi joined the ECP faculty in December as a tenure-track Assistant Professor specializing in pharmacometrics after completing a pharmacometrics fellowship with ECP faculty member Dr. Richard Brundage.

Previously, Dr. Al-Kofahi earned his D.D.S. in Dentistry at the Jordan University of Science and Technology, and his Ph.D. in Physiology from the Department of Molecular and Cellular Physiology at the Louisiana State University Health Sciences Center in Shreveport, Louisiana.

Dr. Al-Kofahi’s research focus is in the analysis and simulation of the pharmacokinetics-pharmacodynamics of biologics; as well as modeling and simulation of circadian rhythms in particular adrenal steroids in children with Congenital Adrenal Hyperplasia.

His expertise is in the areas of pharmacometrics, pharmacokinetics, pharmacodynamics, population pharmacokinetics-pharmacodynamics, modeling and simulation, nonlinear mixed effects modeling, model-based drug development, and modeling biologics.

Dr. Stephanie Huang has joined the ECP faculty as a tenured Associate Professor specializing in pharmacogenomics.

Dr. Huang received her Ph.D. in Clinical Pharmacy in 2005 from Purdue University. From 2005 to 2009 she was a postdoctoral scholar and fellow at the University of Chicago Department of Medicine after which she accepted an Assistant Professor position in the Section of Hematology Oncology, Department of Medicine at the University of Chicago.

Dr. Huang’s research focus is in translational pharmacogenomics with particular interest in the pharmacogenomics of anticancer agents with an ultimate goal of advancing individualized cancer pharmacotherapy. By systematically evaluating the human genomes and their relationships to drug response and toxicity, her goal is to develop clinically useful models that predict risks for adverse drug reactions and non-response prior to administration of chemotherapy. Her innovative research is highly collaborative and adds a unique combination of laboratory-based and translational-oriented science to our existing faculty focusing in the field of pharmacogenomics.

Dr. Huang brings with her ongoing research support for a study titled “Whole Genome Expression Based Drug Repurposing in Metastatic Breast Cancer.” The goal of this continuing project, sponsored by the Avon Foundation, is to generate and compare predicted drug sensitivity scores in different breast cancer tissues from TCGA for all drugs that have been screened in cell lines.
Dr. Elizabeth Hirsch joined the faculty of the Department of Experimental and Clinical Pharmacology in July as a tenure-track Assistant Professor specializing in infectious diseases.

Dr. Hirsch received her Doctor of Pharmacy in 2007 from Creighton University, where she had already earned a Bachelor of Health Sciences. In 2007/2008, she completed an ASHP Accredited PGY1 Pharmacy Residency at St. Luke’s Episcopal Hospital in Houston, followed in 2008 to 2010 by an Infectious Diseases Pharmacotherapy Fellowship.

Dr. Hirsch’s major areas of research include antimicrobial susceptibility testing, antimicrobial pharmacokinetics and pharmacodynamics, rapid diagnostics for bacterial infections and the clinical outcomes of infections. She has been a faculty member at Northeastern University for 5 years, where she has taught in their infectious diseases curriculum. She has been active in publishing her work on bacterial resistance in peer reviewed journals directed at clinical pharmacy and infectious diseases.

Dr. Hirsch is currently working on two projects related to the recently approved antibiotic, ceftolozane/tazobactam. In the first, the in vitro activity of ceftolozane/tazobactam is being assessed against a collection of multidrug-resistant clinical isolates of Enterobacteriaceae and Pseudomonas aeruginosa. In the second retrospective, multi-center study, she is analyzing clinical outcomes following treatment with ceftolozane/tazobactam. Her lab is also investigating an old antibiotic, fosfomycin, which has garnered renewed interest due to its favorable activity against multidrug-resistant organisms. Projects involving fosfomycin combination therapy and resistance emergence are ongoing.
Consistent with the stated strategic goals of the College of Pharmacy and the Department of Experimental and Clinical Pharmacology, ECP is dedicated to the exploration of opportunities to grow its research strengths, graduate training program, and overall global engagement. To these ends, on October 25, 2017, University of Minnesota (UMN) faculty leaders Robert J. Straka (Experimental and Clinical Pharmacology), Jayanth Panyam (Pharmaceutics), Gunda Georg (Medicinal Chemistry), Ling Li (Experimental and Clinical Pharmacology), and Courtney Aldrich (Medicinal Chemistry), on behalf of Dean Lynda Welage, traveled to Nanjing, China for the Second Bilateral Symposium of Faculty between Chinese Pharmaceutical University (CPU) and the University of Minnesota (UMN).

The meeting strengthened the growing relationship between UMN and CPU and allowed faculty leaders to discuss opportunities for engagement in collaborative research among their respective colleges. UMN faculty representatives presented on their respective research programs and those of others from their departments. In addition to profiling their individual scientific interests, representatives discussed collegiate and departmental faculty profiles and mechanisms to support the shared training of graduate students and visiting faculty. The meeting is an outgrowth of the first bilateral symposium in June 2016 hosted by the University of Minnesota’s College of Pharmacy. To continue and strengthen research and educational collaborations between the two institutions, representatives of the two universities are planning the third bilateral symposium for July 2018, hosted by the University of Minnesota’s College of Pharmacy.

University of Minnesota faculty are greeted by CPU representatives at the main research facility on campus. It to rt: Haiying Sun, Chaoyong He, Ting Cai, Gunda Georg, Haiping Hao, Ling Li, Jayanth Panyam, Robert Straka, Courtney Aldrich, Jiang Sheng.
Assistant Professor Melanie Nicol has spent her career pursuing HIV/AIDS research. In recent years, she has focused much of her efforts on researching HIV/AIDS prevention in women specifically, and has begun participating in international partnerships to combat the disease globally. To continue this work, Dr. Nicol was awarded a K08 young investigator career development grant from the National Institute of Health; National Institute for Allergies and Infectious Diseases (NIH NIAID) to study specific factors affecting the efficacy of HIV preventative drugs in women.

Globally, women represent half of new HIV infections, yet few existing female-controlled prevention methods have demonstrated clinical relevance. Truvada ® is currently the only intervention with regulatory approval as a preventive agent, and clinical trials in over 10,000 participants have shown Truvada to be effective in men who have sex with men, serodiscordant couples, and injection drug users, but it failed to demonstrate protection in two separate Phase III trials with over 4000 heterosexual women.

Dr. Nicol’s mentored research will examine commonalities between unprotected women that have been noted in previous research but not studied directly, including hormonal contraception use, elevated levels of inflammatory cytokines in the female genital tract, and differences between the vaginal microbiomes of women who are protected from HIV with currently approved or experimental treatments and those who are not. Her research will provide much-needed data to improve clinical outcomes in future clinical trials.

“Evaluating Antiretroviral Pharmacology in the Female Genital Tract to Optimize HIV Prevention”

K08 Award: $847,011 over 5 years
Sponsor: National Institute of Health; National Institute for Allergies and Infectious Diseases (NIH NIAID)
PI: Melanie Nicol, Pharm.D., Ph.D., Dept. of Experimental and Clinical Pharmacology
Core Mentoring Team:
Paul Bohjanen, M.D., Ph.D. Division of Infectious Diseases and International Medicine
Angela Kashuba, Pharm.D. UNC Division of Pharmacotherapy and Experimental Therapeutics
Jim Hodges, Ph.D. Division of Biostatistics
Robert Straka, Pharm.D. Department of Experimental and Clinical Pharmacology
Additional Content Advisors:
Alexander Khoruts, M.D. Division of Gastroenterology Hepatology and Nutrition
Carrie Terrell, M.D. Department of Obstetrics, Gynecology and Women’s Health
Alumni Spotlight: Heather Vezina, Ph.D. ‘12

Where are you now and how long have you been there?
I work at Bristol-Myers Squibb (BMS) in Princeton, New Jersey. I've been at BMS for four and a half years. I’m an Associate Director in Clinical Pharmacology & Pharmacometrics.

Have you had any recent promotions or major field changes since you began your career?
I was promoted from Senior Research Investigator to Associate Director in May of 2017.

What would you describe is your primary role in your current position?
I'm the clinical pharmacology lead for several programs in oncology and immuno-oncology. I support compounds in all phases of development from first-in-human studies through Phase 3 clinical trials. In this role, I contribute to designing clinical trials, conducting PK/PD data analyses, selecting dosing regimens, and interacting with global health authorities. Not unlike an academic setting, I work in a dynamic and engaging matrix team environment, which includes clinicians, statisticians, biomarker leads, regulatory scientists, and study operations experts.

Since graduating from ECP’s grad program, what would you say are your most significant professional accomplishments? What particular achievement are you most proud of?
After graduating from the ECP graduate program, I transitioned successfully from a career in academics to one in biopharmaceutical research and development. I’ve developed expertise in oncology and immuno-oncology drug development and expanded my skills in pharmacometrics. I’ve also contributed to global regulatory approvals for the immuno-oncology agents, ipilimumab and nivolumab. I’m most proud of the work that I did to support our antibody drug conjugate programs in early development. In 2016 I was recognized with an internal BMS award known as the Pathfinder Award for advancing a novel dosing strategy for antibody drug conjugates in first-in-human studies.

Reflecting back on your experiences as an ECP Graduate Student, what are your fondest memories from that time, and what advice can you give to current and prospective students in ECP?
My fondest memories include working with Dr. Brundage and Dr. Balfour in the clinical virology research program, being part of the inaugural class of K-12 award recipients, decoding NONMEM errors during my thesis work, and having lunch meetings at Bona. My advice to current/prospective students is to seek out experiences in different career settings as part of your training. Everyone’s professional journey is unique - embrace yours and don't be afraid to diversify and try something new.
Faculty Highlights

Grants

Jeffrey Bishop received a grant for $275,000 over two years from the National Institutes of Health National Center for Complementary and Integrative Health for his project, “Epigenetics of PTSD Treatment Response.” Dr. Bishop also received a $25,000 Enhance Comprehensive Pharmacist Services to Improve Patient Health Clinical Research Award in the College of Pharmacy grant for his project entitled "Medication Therapy Management and Pharmacogenetic Evaluation in Mental Health."

Betsy Hirsch received $156,382 from Merck and Company for "A Retrospective Multi-Center Study to Assess Patient Outcomes Following Treatment with Ceftolozane/Tazobactam."

Stephanie Huang received a $2.225M five-year NIH/National Cancer Institute RO1 grant for her project, "Drug Repurposing in Breast Cancer." Dr. Huang also received a grant of $159,908.10 from the Avon Breast Cancer Crusade for her project, "Bridging Pre-Clinical Drug Screening with Patient Genomic Profiles in Order to Accurately Predict Patient Response to Therapy."

Reena Kartha received a $15,000 grant from the United Leukodystrophy Foundation for her project "Therapeutic Effect of Nervonic Acid in Lowering Very Long Chain Fatty Acids in Adrenoleukodystrophy."

Melanie Nicol received $847,011 over 5 years for a K08 award from the NIH National Institute of Allergy and Infectious Diseases for her project entitled "Evaluating Antiretroviral Pharmacology in the Female Genital Tract to Optimize HIV Prevention."

Debra Skaar received a $25,000 Enhance Comprehensive Pharmacist Services to Improve Patient Health Clinical Research Award in the College of Pharmacy for her project entitled "Creating a 21st Century Precision Medicine Intensive Care Unit (ICU)."

Beshay Zordoky was appointed Masonic Cancer Center Women's Health Scholar by the Women's Health Research Program. This $250,000 career development award includes participation in all training activities of the Building Interdisciplinary Women's Health Research Program (BIRCWH).

Recognition

James Cloyd received the 2017 University of Minnesota Pharmacy Alumni Society Faculty Recognition Award for his contributions to the University of Minnesota Alumni Association, alumni, the College of Pharmacy, the University of Minnesota, and the profession of pharmacy.

Jeannine Conway was named PharmD Teacher of the Class by the PharmD class of 2018.

Betsy Hirsch received a 2017 Young Investigator Award from the Society of Infectious Diseases Pharmacists in recognition of past research accomplishments and to acknowledge her promise as a researcher in the broad area of infectious diseases.

Stephanie Huang was named a Featured Investigator by the Pharmacogenomic Research Network for January, 2018.

Reena Kartha was awarded a 2nd year fellowship from the Lysosomal Disease Network (LDN) which will allow her to continue and expand her research related to oxidative stress and inflammation in Gaucher Disease.
Engagement

Stephanie Huang was a keynote speaker at the 2018 Rho Chi Research Day on February 13, where she presented “Leverage High Throughput Data for Pharmacogenomic Discovery and Drug Repurposing.”

Melanie Nicol’s lab group and some colleagues braved sub-zero temperatures on February 10th to participate in the 2018 MN AIDS Walk as team “HIV Kinetics,” where they raised over $600 for essential programs that support people with or at risk for HIV infection.

Media

Ramaiah Muthyala’s “Rare and Ignored,” a commentary on rare diseases’ lack of visibility among public health researchers, was published in the newspaper The Hindu (www.thehindu.com) on January 28, 2018.

Dr. Stephanie Huang

Ramaiah Muthyala helped to orchestrate the inaugural World Rare Disease Day conference in New Delhi, India, on February 28th. The conference had four sessions: Industry, Research, Policy, and Patient Perspectives. Attendees included Indian government officials Union Health Minister J.P. Nadda and Union Minister Dr. Jitendra Singh.
Congratulations to ECP graduate students Ali Alhadab, David Hottman, Christina Peterson, and Youssef Roman on their successful dissertation defenses!

Samuel Callisto was the featured student profiled in the February International Society of Pharmacometrics newsletter.

Irene Vuu received an Early Career Grant from the American Epilepsy Society (AES). She was recognized on December 1st at the AES Research Grantee & Alumni Reception.

Jay (Ya-Feng) Wen and Samuel Callisto are assisting in the planning of the Second Bi-Annual Pharmacogenomics Conference, which will be held on campus this June. (See pg. 11)

Jay (Ya-Feng) Wen is a coauthor of the hypertension chapter of Pharmacotherapy Principles and Practice, 5th ed. (currently in editing). He is currently working with department head Robert Straka on the Very Important Pharmacogenes in Hmong (VIP-H) Study. This study will explore potential differences in allele frequencies between the Hmong and non-Hmong for select genetic variations within key pharmacogenes known to influence drug response.

Irene Vuu (lt) at AES Research Grantee & Alumni Reception

Jay (Ya-Feng) Wen and Samuel Callisto are assisting in the planning of the Second Bi-Annual Pharmacogenomics Conference, which will be held on campus this June. (See pg. 11)

ECP faculty Robert Straka and Melanie Nicol, along with graduate students Natalie Schmitz and Jay (Ya-Feng) Wen, hosted a meet-up for outstanding ECP and Pharmaceutics alumni at the 2018 ASCPT meeting in Orlando, FL, March 21-24. Graduates have made significant impacts in the disciplines of Clinical Pharmacology, Pharmacometrics, Pharmaceutics, and Drug Development, both nationally and internationally. Great to see all of you there!
Registration is open for the second biennial Precision Medicine Conference!

**Pharmacogenomics: Genomic Testing to Individualize Drug Therapy**

**Friday, June 22, 2018**

Pharmacogenomics (PGx) is the science of how an individual’s genetic background impacts response to medications. The field is now quickly emerging as a tool for clinical care. Although the field of PGx has existed for over 30 years, most clinicians remain unsure how to use PGx information.

This one-day conference will provide education on a range of topics including cancer somatic mutations and selection of targeted therapies, emerging PGx areas such as analgesics and how to apply PGx in minority populations, clinical PGx guidelines, use of PGx in children, implementation of PGx in practice settings, insurance reimbursement, evidence for cost effectiveness, and improved quality of care.

Registration and additional details online at: [https://z.umn.edu/individualize-drug-therapy](https://z.umn.edu/individualize-drug-therapy)

Continued from page 10

ASCPT meet-up attendees, L to R: Vijay Ivaturi (University of MD), Youssef Roman (University of HI), Kyle Baron (Metrum), Ghada Ahmed (Astra Zeneca, UK), Natalie Schmitz (University of MN), Melanie Nicol (University of MN), Ahmed Salem (AbbVie, IL), Robert Straka (University of MN), Vikas Kumar (Pfizer, NY), Akshanth Polepally (AbbVie, IL), Rajendar Mittapalli (AbbVie, IL), Nael Mostafa (AbbVie, IL), Suresh Agarwal (AbbVie, IL), Manoj Chiney (AbbVie, IL), Jay Wen (University of MN). Not pictured: Manisha Lamba, Ali Alhadab