ECP Gazette

Spring 2024





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ECP Gazette

FACULTY

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Shen Cheng, PhD Professor

James C. Cloyd, PharmD Professor; Weaver Endowed Chair; Director, Center for Orphan Drug Research

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Elizabeth Hirsch, PharmD Associate Professor

R. Stephanie Huang, PhD Professor

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Michael Kotlyar, PharmD Associate Professor

Ilo E. Leppik, MD Professor Ling Li, PhD Professor; VFW Endowed Chair

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DEAR FRIENDS,

Welcome to our latest newsletter, where we proudly showcase the exceptional achievements within our ECP Department. Our dedicated faculty, outstanding graduate students and hardworking staff continue to exemplify excellence in the field. Our esteemed faculty members have been at the forefront of groundbreaking scientific advances employing creative and innovative teaching approaches and sharing our best work at national and international venues. The quality of the individuals within our department drives our reputation through influential publications that advance society's understanding of clinical pharmacology. Continuous improvement of our delivery of critical content to our professional students advances through the new MNSpire curriculum, while we look to optimize delivery of coursework and research experiences within our graduate program to train the next generation of leaders of translational research.

In this edition of our newsletter, in addition to recognizing the consistent flow of accomplishments from our faculty, students, alumni, trainees, and staff, we are pleased to welcome Dr. Shen Cheng as our most recent hire in the field of pharmacometrics, while we bid a bittersweet farewell to retiring faculty member Dr. Susan Marino.

Our mission to improve healthcare for Minnesotans and beyond continues in the current climate challenging externalities. These include but are not limited to political, economic and societal issues. In spite of significant headwinds, we continue to advance with the confidence that we are united in our motivation to improve the health and wellbeing of members of our community through our research, teaching and service.

I hope you enjoy reading our ECP newsletter featuring several highlights of which we are all proud to share. I take considerable pride in serving as department head for ECP and will continue to support our team to the best of my ability going forward. I am also grateful for the support of so many others in the department who facilitate the accomplishments of our department's goals, including associate Department Head's Drs. Pam Jacobson and Ling Li and our outstanding staff, including Zack McGough, Becky Palapala and Lori Endsley. Finally, the leadership in our graduate program, which is critical to our success, comes from Drs. Angela Birnbaum as DGS and Melanie Nicol as associate DGS who are expertly supported by Susan Williford.

Have a safe and pleasant spring and summer season--a time for new growth and development for all--as you enjoy this edition of our ECP newsletter.

Sincerely,

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Robert Straka, PharmD Professor and Department Head

COMINGS & GOINGS



FAREWELL DR. MARINO! Contributed by Angela Birnbaum

Dr. Susan Marino completed her phased retirement in February. Dr. Marino has a vast depth of scientific knowledge, though it is her background with a wealth of diverse experiences that have made her not only a topnotch scientist, but also a very interesting person.

Susan had an unconventional career and a different background than typical faculty. For formal training, she received her BA with a major in psychology and minor in philosophy from NYU. She then completed a PhD in Neurobiology and Behavior from University of Pennsylvania.

She obtained funding from NIH for a postdoctoral fellowship to study the neuroanatomy of the gustatory cortex (taste) while she and her husband, Gordan, lived in Copenhagen during the two years he had a Woodrow Wilson fellowship studying the Danish philosopher Søren Kierkegaard. She was also an Associate Research Scientist at Yale School of Medicine, where she worked in Psychometrics and genetics research characterizing taste thresholds. During this time, she was involved in computer modeling and genetics research. Dr. Marino also spent time as a high school teacher in Maine and is familiar with various teaching methods and development of curriculum which has been useful in both pharmacy and graduate programs at the U of M.

Eventually, Gordan accepted a job at St. Olaf and Susan was offered the director's position for the Program for Women in Science at the University of Minnesota in the Institute of Technology, now the College of Science and Engineering. In this position, she was able to establish successful pre-college outreach programs and build strong ties with women students and faculty. It was this position that gave her the opportunity to develop initiatives on diversity at the University and informed her service role in diversity in the College of Pharmacy. During her role as the program director, she regularly gave presentations around campus, and the University of Minnesota's Vice Provost at the time was so impressed that she asked Susan to create a freshman seminar course. The title of the course was "Pills for Every Problem or Problem Pills," which became very popular. It was this seminar course that attracted pharmacy students and piqued Susan's interest in the College of Pharmacy.

In order to make the shift to a faculty position, she needed to identify a mechanism for funding, but the mechanism she identified was only available to those 1 to 5 years outside of a training position. The group she found willing to hire her as a research associate was with Jim Cloyd and Ilo Leppik, current faculty members in ECP. It was during this initial stint in ECP that she received a supplement to a P50 through the NIH's Reentry to Biomedical and Behavioral Research Careers program. This supplement produced preliminary data for a K01 Mentored Career Development Award, which then led to an R01 and several pharmaceutical company grants. She also received one of the first government stimulus grants that funded a summer program for high school and undergraduate students in the college.

During the time of her RO1, she was recruited to the University of Florida as a tenured track Assistant Professor in Pharmacotherapy and Translational Research in the Center for Pharmacogenomics in the College of Pharmacy. Fortunately, she returned to Minnesota after a few years, and she has trained students in research to investigate the variability of cognitive responses to medications ever since.

In addition to her broad academic background, Susan is well versed in other important topics such as boxing, football, and music. Although she will be retired, we plan to see Susan around, participating in both research and teaching as an emerita.

COMINGS & GOINGS



WELCOME SHEN CHENG!

Dr. Cheng is a 2021 graduate of the department's graduate program, where he majored in pharmacometrics and minored in biostatistics. His thesis work used a pharmacometric modeling approach to investigate the impact of pharmacogenetic differences in drugdrug interactions (DDIs). Upon graduating, Cheng joined the Metrum Research Group, an international biomedical consultancy group, where he has supported drug modeling and simulation for the pharmaceutical industry.

Dr. Cheng will be a welcome addition to the faculty members in the ECP department, where the goals are to lead in the innovation, development and application of pharmacometric modeling which aids in forecasting drug response so as to optimize therapeutic outcomes. Check out the faculty spotlight in this issue of the ECP Gazette to learn more about Dr. Cheng and his work!

2023-2024 FELLOWSHIP RECIPIENTS



James C. Cloyd Neuropharmacology Fellowship Chenxu Li (faculty advisors: Reena Kartha and Lisa Coles)



Bighley Graduate Fellowship Yingbo Huang (faculty advisor: R. Stephanie Huang)



Coin Foundation Fellowship Tiffany Chang (faculty advisors: Elizabeth Hirsch and Melanie Nicol)



ECP Fellowship Lusi Zhang (faculty advisor: Jeffrey Bishop)



Olsteins Graduate Fellowship Lusi Zhang (faculty advisor: Jeffrey Bishop)

Bighley Graduate Fellowship

(faculty advisor: R. Stephanie Huang)

Yuting Shan



Robert J. Straka Fellowship Boguang Sun (faculty advisor: Robert Straka)

RARE DISEASE DAY 2024



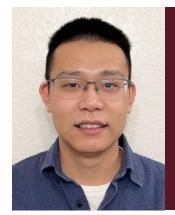
The twelfth annual Rare Disease Day at the University of Minnesota was co-hosted by the Center for Orphan Drug Research (CODR) and the Stem Cell Institute (SCI) on Thursday, March 7, 2024. Nearly 250 people joined the event, either virtually or in-person at the McNamara Alumni Center. The program was titled "Orphan Products for Rare Diseases: Availability and Accessibility - They're Not The Same Thing."

The first keynote speaker, David Fajgenbaum, MD, MSC, DMBA, addressed the issue of availability of orphan products, while the second speaker, Dave McLean, PhD, discussed the issue of accessibility of orphan products. The keynote speakers were then joined by Amy Marquez, Center for Bleeding and Clotting Disorders at M Health Fairview, and Liz Reyer, Minnesota State Representative (District 52A), for a panel discussion moderated by Erica Barnes, Executive Director of the Minnesota Rare Disease Advisory Council. University of Minnesota Interim President, Jeff Ettinger, provided a recorded welcome, which highlighted the University's prominent and growing role in providing rare disease clinical care and research. In addition to the formal program, CODR and SCI hosted a breakfast session for representatives of patient advocacy organizations that featured Sue Berry, MD, Chair of the University of Minnesota/M Health Fairview Rare Disease Center of Excellence, who discussed the establishment of and plans for the University of Minnesota/M Health Fairview Rare Disease Center of Excellence.

Congratulations as well to the Rare Disease Day Research Award recipients: Miles Greenberg, St. Olaf College; Katelyn Sawyer, Medical School; Bryan Yan, College of Pharmacy; and, Adeboye Bamgboye, College of Pharmacy.

Thank you to everyone who presented posters, hosted tables, joined us for the program, and sponsored the event - your support made it all possible. A special thanks to the planning committee members: Erica Barnes, Jim Cloyd, Lisa Coles, Lori Endsley, Skyler Jackson, Reena Kartha, Sue Keirstead, Christine Kiel, Linda Krach, Robert Kriel, and Paul Orchard.

ECP SPOTLIGHT: FACULTY



SHEN CHENG

Please describe your academic background and how you came to the faculty of ECP.

My academic journey started with a BS degree in Biological Sciences from Soochow University in China. I then moved to the US and obtained a MS degree in Pharmacology from the University of Michigan. While I was working on the in vitro drug metabolism research at the University of Michigan, I gradually developed an interest in using the approach of modeling and simulation (i.e., pharmacometrics) to characterize the drug dispositions (e.g., drug metabolism) to realize precision medicine. This led me to move on and pursue a PhD degree in Experimental and Clinical Pharmacology (ECP) at the University of Minnesota, an internationally leading program in the field of individualized medicine. My PhD thesis work was conducted under the mentorship of Drs. Richard Brundage and Mahmoud Al-Kofahi, where my research mainly focused on using pharmacometric approaches to quantitatively assess the impact of pharmacogenetics on clinical drug-drug interactions (DDIs). Through my PhD training, I gained extensive exposures in pharmacokinetic (PK) / pharmacodynamic (PD) modeling, pharmacometric statistics and clinical trial simulations.

After completing my PhD, I started my work as a Research Scientist at Metrum Research Group (MetrumRG), a renowned biomedical modeling and simulation consultancy. While working at MetrumRG, I worked in close collaboration with many pharmaceutical companies to develop and implement state-of-art pharmacometric methodologies, accelerating the development of innovative therapeutics. My experience in modelinformed drug development (MIDD) at MetrumRG has equipped me for my role as an Assistant Professor in Pharmacometrics. I am eager to contribute to the training and research program in pharmacometrics at the ECP Department of the University of Minnesota.

What types of projects are you currently working on, and/or what projects do you hope to pursue initially?

In general, my research interests are deeply rooted in the field of pharmacometrics, incorporating both the development of methodologies and their practical implementations. Over the years in both academia and industry, I have been involved in a variety of pharmacometrics projects across multiple disease areas (oncology, rare diseases, cardiovascular diseases, etc) in diverse populations (pediatric patients, patients with obesity, patients with renal dysfunction, etc) across several types of therapeutic modalities (small molecules, biologics, cell therapies, etc) and across different phases of drug development (preclinical phase, early / late clinical phase, etc). These experiences have been instrumental in shaping my research interest in model-informed drug development (MIDD) and modelinformed precision dosing (MIPD) to enhance precision in treatment.

I am serving as a pharmacometrician for several ongoing research projects. One of them is to develop PK / PD models for cortisol for the treatment of congenital adrenal hyperplasia (CAH) in pediatric patients using a pulsatile pump and evaluating a clinically relevant exposure-response (ER) relationship. Another ongoing collaborative project is to develop mechanistic PK models for mycophenolate mofetil and its metabolites to tailor clinical dosing for transplant patients by integrating their unique pharmacogenomic and pharmacomicrobiomic profiles, aiming for improved treatment efficacy. Looking ahead, I'd like to advance the field of quantitative research further and continue developing quantitative research to achieve individualized medicine for optimizing safety and efficacy. Part of the vision also includes developing new methodologies for pharmacometrics analysis, particularly focusing on the integration of pharmacometrics with real-world data such as electronic health records.

How did you arrive at these topics as a focus for your research? What makes them appealing to you?

While I was working as a student in the field of drug metabolism, I was introduced to the concepts of pharmacometrics through literature. As a junior graduate student, I was captivated to see the application of quantitative models leveraging in vitro and in vivo drug metabolic information to predict drug exposures in a physiologically relevant manner. My fascination with pharmacometrics deepened as I came to understand that drug metabolism is merely one aspect of its broad utility. The area of pharmacometrics became much more appealing when I witnessed its rapid growth and its widespread application in enhancing therapeutic effectiveness and driving drug development decisionmaking across various disease states and diverse populations to achieve precision medicine. I am particularly intrigued by the development of cutting-edge pharmacometric methodologies incorporating innovative statistical concepts to characterize the variability and uncertainty present more accurately in the experimental and clinical data.

What is your vision for the way your research might affect patient care or outcomes? What topics/research paths would you like to explore in the future?

In the future, I am hoping to continue developing pharmacometric research at the ECP department, extending its application across various disease areas accessible to our institution and beyond. These pharmacometric research projects are promising in generating impactful clinical decision support (CDS) tools for the optimization of therapeutics for disease treatment. Additionally, I am eager to use the developed models to prospectively inform the design of future preclinical and clinical studies, ultimately leading to more efficient study design.

In addition, simulation is a pivotal concept in pharmacometrics. Besides satisfactorily characterizing the data and identifying clinically important covariates, a fascinating feature of a pharmacometrics modeling is its capability of conducting extrapolation (exploring clinical scenarios not directly studied) by carefully designing a simulation. This expands the potential for integrating pharmacometric models with diverse 'big data' sources, such as electronic health records and omics data, to predict exposures and responses that are otherwise challenging to obtain in clinical environments. Therefore, as another topic of interest, I am hoping to develop new methods to explore the possibilities of appropriately integrating well-developed pharmacometric models with real world data. The successful execution of this research will enhance our understanding of exposureresponse relationships on a wider scale and lead to the identification of novel covariates and biomarkers that are crucial for therapy optimization.

2023-2024 GRADUATES



Ibrahim Abdelgawad, PhD Thesis: Molecular Mechanisms and Cardiovascular Ramifications of Doxorubicin-induced Senescence



Charul Avachat, PhD Thesis: Pharmacokinetic Characterization of Antiseizure Medications at Different Stages of Life in Women with Epilepsy



Morgan Bixby, PhD Thesis: Investigation of Klebsiella pneumoniae inner colonies during fosfomycin susceptibility testing

Yingbo Huang, PhD Thesis: Unveil Molecular Underlying Causes of Observed Sex Differences in Human Complex Traits and Cancer



Complex Traits and Cancer

Boguang Sun, PhD Thesis: Advancing Precision Medicine: Harnessing Data from Diverse Sources and Subjects to Predict Medication Efficacy and Safety

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R. Stephanie Huang





Michael Kotlyar

Ramaiah Muthyala

Jeffrey Bishop was invited as one of three overseas experts to attend the West China International Forum for Schizophrenia Research in Chengdu City, Sichuan Province, China. This event was hosted by Sichuan University West China Hospital, a top academic medical center in China. Dr. Bishop's presentation on using genomic and blood-based biomarkers to uncover mechanistic insights and clinical implications of schizophrenia and related psychotic disorders was wellreceived by esteemed colleagues in the fields of psychiatry, psychology, and brain imaging, both in the United States and China. ECP graduate student Lusi Zhang also attended the event alongside her advisor, Dr. Bishop. They actively interacted with faculty members and trainees at the West China Hospital Department of Radiology and discussed various ongoing and prospective interdisciplinary collaborative projects.

Scott Chapman was co-author on the NIH NCATS CTSA news article, "National COVID Cohort Collaborative (N3C) Cardiovascular Disease Domain Team Makes Early Discoveries in Link Between COVID-19 and Cardiovascular Disease." (Link below)

Elizabeth Hirsch was awarded with the distinction of Fellowship in the Society of Infectious Diseases Pharmacists (SIDP). FIDP recognizes outstanding SIDP members with significant and sustained contributions to infectious diseases and the mission of SIDP. Successful applicants demonstrate a commitment to promoting the appropriate use of antimicrobials for the prevention and management of infectious diseases through leadership and collaboration in infectious diseases practice, education, research, and advocacy. Dr. Hirsch was also appointed to an Associate Editor role at the infectious diseases journal, JAC-Antimicrobial Resistance. This is a fully open access Society journal from the British Society for Antimicrobial Chemotherapy (BSAC), and sister journal to JAC (Journal of Antimicrobial Chemotherapy).

Stephanie Huang's lab was awarded the Microbiome and Cancer Symposium Seed fund. Dr. Huang is also awarded a new Masonic Cancer Center CRTI Exceptional Translational Research Award. She is the co-PI along with Dr. Emmanuel Antonarakis on this new grant, titled "ATM inhibition for the treatment of TP53-altered metastatic prostate cancer: a novel synthetic lethality".

Reena Kartha received a Grant-in-Award from OVPR to purchase a Seahorse instrument. The award comes with 2 UROP-funded positions. Matching funds were provided by CoP, ECP, CODR, Li lab, the Stem Cell Institute, and the Department of Ophthalmology & Visual Neuroscience.

Michael Kotlyar is a co-lead (with Serguei Pakhomov from PCHS and Sandra Japuntich from Hennepin) on a project titled "Feasibility of Using a Culturally Tailored Conversational Agent for promoting smoking cessation treatment utilization in African Americans who Smoke". This project funded by the National Institute on Minority Health and Health Disparities (NIMHD) is a supplement to the C2DREAM center grant led by Michele Allen in Family Medicine.

On Sept 21, 2023, **Ramaiah Muthyala** attended the formal side event, "Universal Health Coverage a Reality for People Living with Rare Diseases," organized by Rare Disease International (RDI) together with the Permanent Mission of Spain

FACULTY NEWS





and Sweden to the United Nations in New York, the Ministry of Public Health -Qatar, EURORDIS, Agrenska, and the NGO Committee for Rare Diseases and the UN Member States. The event included impassioned and informative speeches from Her Majesty The Queen Letizia of Spain, Her Majesty The Queen Silvia of Sweden, Health Minister from Qatar, Assistant Director-General of the World Health Organization, a Senior Economist from the The World Bank and many others, along with our own RDI Chair Durhane Wong-Rieger, Founder, Treasurer & Policy Committee Chair Yann Le Cam and CEO Alexandra Heumber Perry.

Melanie Nicol and Elizabeth Hirsch received the CoP's 2021/2022 Above and Beyond Award for their contributions and commitment toward immunization efforts.

Beshay Zordoky has received two grants: the Masonic Cancer Center Brainstorm Pre-R01 Award (\$100,000) entitled "The Role of Immunosenescence in Delayed Anthracycline-induced Cardiac Complications" and Minnesota Lions Childhood Cancer Foundation Survivorship grant "Role of Immunosenescence in Delayed Cardiac Complications of Chemotherapy" Dr. Zordoky has also been appointed a Faculty Mentor of the Functional Multi-omics of Aging Training Grant (FMATG), starting May 1, 2024.

ECP PICKLEBALL DECEMBER 14, 2023



STUDENT NEWS











Yuting Shan







Yingbo Huang



Abdelrahman Saqr

Boguang Sun

Charul Avachat was married on 20th December 2023.

Tiffany Chang and her teammates Molly Roettger (Dentistry) and Ingri Ramirez-Martin (Public Health) achieved third place in the CLARION local case competition and collectively earned a \$1,000 scholarship. This year's challenge tasked teams with devising an implementation strategy for a hypothetical future pandemic affecting a school, longterm care facility, or livestock facility, requiring teams to draw insights from the lessons gleaned from the recent COVID-19 pandemic.

Mary Raphel Daniel won the People's Choice Award at the College of Pharmacy's 3 Minute Thesis Competition.

Yingbo Huang, graduate student in Stephanie Huang's lab, has been awarded the COGS travel award to present his work at the ASHG annual meeting.

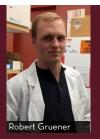
Yuhan Long, graduate student in the lab of Angela Birnbaum, was awarded a 2023 American Epilepsy Society (AES) Young Investigators Award. In addition to a standard poster presentation, Long's abstract was also selected as a platform presentation and as a poster at the Broadening Representation and Inclusion by Growing Diversity and Equity (BRIDGE) poster session at the American Epilepsy Society Annual Meeting.

ECP grad students Abdelrahman Sagr and Yuting Shan took 1st and 2nd place, respectively, in the College of Pharmacy's Rho Chi Research Day poster competition for the Twin Cities campus for their projects, ""Deciphering the Gut Microbiome's Role in Pharmacokinetics: Insights from a Semi-Mechanistic Population Pharmacokinetic Model of Mycophenolate Mofetil in Transplant Recipients" (Saqr) and "Sex Differences in Intratumor Microbiome Have Implications on Disease Outcomes and Treatment Response" (Shan).

Boguang Sun's summer intern project at AstraZeneca, "Application of Machine Learning Combined with POPPK and QSP Models for Adverse Events Risk Prediction of a CD19targeting Bispecific Therapy," has been accepted for presentation and will be receiving a Presidential Trainee Award at the ASCPT 2024 Annual Meeting to be held March 27-29, 2024, in Colorado Springs, CO. In recognition of this high-quality abstract, Boguang has also been chosen as a recipient of a Top Poster Ribbon.

Lusi Zhang, a 3rd-year PhD student, was invited by the Department of Pharmacy of Xi'an Mental Health Center, the largest psychiatric hospital in northwestern China located in Xi'an, the capital city of Shaanxi province. Lusi gave a talk entitled "Psychiatric pharmacy practice in the United States: My learnings through PharmD-PhD training at University of Minnesota" and discussed ideas of potential future collaborations. Zhang was also appointed to the Communications Committee of the Pharmacogenomics Global Research Network (PGRN). This appointment is for 3 years.

AROUND THE DEPARTMENT





Vijay Ivaturi



Kinjal Sanghav



Weijie Zhang

Benu George (a postdoctoral fellow at the Zordoky lab) won second place for best oral presentation at the CoP postdoctoral appreciation day in November, 2023. Dr. George will embark on a new opportunity as a postdoctoral fellow at Baylor College of Medicine in 2024.

Robert Gruener, a postdoc in Stephanie Huang's lab, has been selected to receive the NIH T32 (Targets of Cancer Training Program) postdoc Fellowship.

ECP alumnus **Vijay Ivaturi** is the new president of the International Society of Pharmacometrics (ISoP).

Holly Korthas, a postdoctoral research associate in the Li Lab, received the postdoctoral fellowship from the NIH T32 Training Grant "Functional Multi-omics of Aging" (FMATG). The period of support is effective November 1, 2023 through October 31, 2024, with the opportunity for a second year of support pending fulfillment of requirements. Dr. Korthas also received the First Place Award for her short talk, "Does APOE connect COVID-19 to Alzheimer's Disease?" at the CoP Postdoctoral Appreciation Luncheon.

Lauren Lee, an undergrad student, was awarded the Undergraduate Research Opportunities Program (UROP) award to conduct research in Stephanie Huang's lab in spring 2024.

Ajibola Opakunle, a graduate student in Molecular Pharmacology and Therapeutics in Dr. R. Stephanie Huang's lab, has been selected to join the All of Us University of Arizona-Banner Health's Data Fellows Program.

Jaehyeok Roh, a post-doctoral fellow in the lab of Reena Kartha, won third place for his short talk, "N-acetylcysteine, a potential adjunctive therapeutic option for Gaucher Disease," at the Postdoctoral Appreciation Luncheon in November, 2023.

ECP alumna **Kinjal Sanghavi**, PhD was promoted to Director of Clinical Pharmacology and Quantitative Sciences at Genmab.

Weijie Zhang, a graduate student in Bioinformatics & Computational Biology in the lab of Stephanie Huang, has been awarded the COGS travel award to present his work at the AACR-NCI-EORTC 2023 International Conference on Molecular Targets and Cancer Therapeutics.

On February 24th, ECP graduate students and trainees gathered for a fun teambuilding and social event at Goldy's Gameroom in Coffman Memorial Union. The group enjoyed food and fellowship, as well as a little friendly bowling competition!



