



# 2018 ANNUAL REPORT

DEPARTMENT OF  
PHARMACEUTICAL  
OUTCOMES AND  
POLICY



# LETTER FROM THE CHAIR

*Dear friends, alumni, collaborators and colleagues,*

Welcome to the first edition of the department of pharmaceutical outcomes and policy annual report. Those of you who have known us for decades would not recognize the new department that has evolved over the past few years. Several of our long-term faculty have retired, and new faculty have begun to emulate and expand their accomplishments in research, training and service. We also have the incredible fortune to have strong college leadership who believes in the value of our work, and we have been able to grow our faculty beyond its original numbers. I became chair of a department with six faculty, which has grown to nine. Please check out the profiles of Karam Diaby, Jenny Lo-Ciganic and Scott Vouri who have joined us this past academic year. Regarding our “veteran” junior faculty who joined the previous academic years, I am pleased to say that all now have a career development award and have started to build impressive research programs: Please check out the stories about Josh Brown, Haesuk Park and Jenny Wei.

As a new chair, I had the incredible opportunity, along with my faculty, to develop and implement a new vision, and I have focused our work on what we can do best: use big data to generate real-world evidence on drug safety, effectiveness and value, drug use quality and related policy to improve public health. We have expanded our collaborations with a variety of disciplines with exciting new extramurally funded work jointly conducted with precision medicine, pharmacometrics and digital health. We have continued our excellence in pharmacoepidemiology but also expanded our reach in pharmacoeconomics and health service research. Pharmaceutical analytics, and specifically the development of prediction models as a tremendous enhancement of clinical decision support, are growing areas of expertise. Clinically, we continue our focus on vulnerable populations in geriatrics, pediatrics and pregnancy, mental health and pain and addiction. Areas in infectious disease and cancer also are growing.

Despite our transition period, our graduate program has remained one of the strongest and largest in the country. We are now recruiting directly into a thesis master’s degree that allows seamless transition into our Ph.D. program. I am particularly pleased to report that all of our Ph.D. graduates found incredible positions, and I am deeply moved to watch this brilliant and diverse group of scientists thrive in our profession. Our online M.S. program continues its strength in applied pharmacoeconomics and pharmaceutical regulation, but you may want to check out our new specialization in managed care pharmacy systems and a completely revamped curriculum in patient safety. In this past academic year, we graduated 36 students in our online M.S. program.

I hope we have a chance to meet in Gainesville, nationally or internationally, at the many academic, professional and government organizations where “POPers” have assumed significant presence. Please consider joining us for our ISPE Gator Dinner or at the reception we are planning at the next North-American ISPOR meeting. As we are growing and expanding our vision, we will reach out for more input and collaboration. I hope you stay close to our department and if you have not been in Gator country for a while, please consider visiting us in 2019.

Go Gators,

**ALMUT WINTERSTEIN, R.PH., PH.D., FISPE**  
Dr. Robert and Barbara Crisafi Chair and Professor



## PUBLIC HEALTH IMPACT SPANNING OVER 30 YEARS OF GRADUATE TRAINING, RESEARCH AND SERVICE

**The department of pharmaceutical outcomes and policy excels in three areas of specialization in research and training. Each area employs its own set of methodological approaches, but all use the vast array of big data sources available in the department.**

1. **Pharmacoepidemiology and Safety Sciences** applies epidemiologic methods and knowledge to the study of uses and effects of drugs in populations after drug approval. Important research areas include post-marketing safety studies, comparative effectiveness studies and predictive models of drug outcomes and use.
2. **Pharmacoeconomics and Outcomes Research** assesses the value (clinical and economic) of pharmaceutical products and related services in the delivery of health care. It aims to provide patients, providers and payers with evidence to inform decision making. Important research areas include economic evaluations, budget impact analysis, multicriteria decision analysis and policy evaluations related to drug formulary, reimbursement and pricing.
3. **Pharmaceutical Health Services Research** examines the quality, accessibility and delivery of pharmaceuticals and related services. The program places emphasis on vulnerable populations, such as children, elderly, minorities and persons with high-burden diseases and disabilities. Examples of research include the development of quality measures or assessment of determinants of appropriate therapy.







## UF AND HARVARD RESEARCHERS SECURE FDA GRANT TO ASSESS MEDICATION SAFETY DURING PREGNANCY

The U.S. Food and Drug Administration has awarded the Harvard Brigham and Women's Hospital and the University of Florida College of Pharmacy a nearly \$3 million grant to develop methods for the assessment of medication safety during pregnancy. The study will enhance the FDA's capability to conduct drug safety studies on maternal and infant outcomes involving exposure to medications during pregnancy.

Almut Winterstein, Ph.D., a professor and chair of pharmaceutical outcomes and policy in the UF College of Pharmacy, and researchers at Harvard's Program in Perinatal and Pediatric Pharmacoepidemiology, will develop and validate Medicaid-specific algorithms to estimate gestational age for live birth pregnancies. In addition, they will develop analytical tools to assess the impact on risk estimates of exposure misclassification, outcome misclassification, selection bias and residual confounding in pregnancy drug safety studies.

Pregnant women are generally excluded from clinical trials due to concerns about drug safety for mothers and children, which makes this population one of the most important targets for post-marketing observational studies. Observational studies take advantage of the fact that exposure to drugs during pregnancy will inadvertently happen in real life. Because of the biology of fetal development, drug exposure may have different effects at different times of pregnancy, which means that accurate timing of conception is critical to fully describe and quantify drug risk. Since conception is typically unknown, gestational age is used to approximate conception. This study will develop tools that improve current estimates of conception and allow sensitivity analysis to assess the degree of bias that may affect drug safety studies because of inaccurate measurement.

## GRANTS

DEPARTMENT FACULTY HAVE DOUBLED THEIR EXTRAMURALLY FUNDED RESEARCH IN RECENT YEARS AND ARE ACTIVELY INVOLVED IN 15 GRANTS AND CONTRACTS

### Pharmacological Management of Pain in Alzheimer's Disease and Related Dementia (ADRD)

NIH/NIA 1K01AG054764-01A1 (K01) Mentored Research Scientist Development Award

Principal Investigator: Jenny Wei  
8/1/17 – 6/30/22 (\$621,865)  
This project aims to provide preliminary data that improve our understanding of current pain medication prescribing and potential discrepancies between practices and pain guidelines, and to formulate hypotheses for future research regarding the role of pain control in reducing mental health problems in ADRD.

### Safety and Effectiveness of Medical Marijuana Utilization in Florida

Principal investigator: Almut Winterstein  
7/1/2017 – 6/30/2019 [\$1,693,525, State of Florida (direct appropriation)]  
This study will describe characteristics of medical marijuana users and their neighborhoods, and evaluate the safety and effectiveness of medical marijuana; and conduct research on drug-drug interactions considering prevalent marijuana co-medication pattern in medical marijuana registry patients.

### Developing the Capability of Using National Medicaid data for FDA Post-Marketing Surveillance to Assess Medication Safety During Pregnancy

HHSF2232014000431  
Principal investigator: Krista Hybrechts  
Principal investigator for UF subcontract: Almut Winterstein  
9/30/2017 – 9/29/2020 (\$500,916 – UF portion)  
This study will develop and validate Medicaid-specific algorithms to estimate gestational age for live birth pregnancies, explore methods to identify other pregnancy outcomes and develop analytic tools to assess the impact of exposure misclassification, outcome misclassification, selection bias and residual confounding (due to missing covariates in EHD).

### Genomic Medicine Implementation: The Personalized Medicine Program – administrative supplement - U01

HG007269-0452  
Principal investigator: Julie Johnson

Co-investigator: Almut Winterstein  
9/7/2017 – 4/30/2018 (\$610,207)  
The purpose of the main administrative supplement request is to seek funding to advance a variety of cross-network analyses and projects that should significantly advance pharmacogenomic implementation and the IGNITE network.

### The Child Health Quality (ChEQ) Partnership Program

U18HS025298  
Principal investigator: Elizabeth Shenkman  
Co-investigator: Almut Winterstein  
9/30/2016 – 9/29/2020 (\$2,638,534)  
This study will test the feasibility and usability of children's quality of care measure sets through field testing and translating results into QI goals and multilevel performance improvement projects. In addition, it will implement and disseminate leading-edge methods to evaluate and compare quality of care at state, health plan and provider levels.

**Real-Time Risk Stratification of Hypo- and Hyperglycemia to Enhance Glucose Management Outcomes in Hospitals**  
HHSF-223-2015-10118C [FDABAA-15-00121]  
Principal investigator: Almut Winterstein  
9/30/2015 – 9/29/2017 (\$296,477)  
This study will evaluate the effectiveness of an EHR-based algorithm that ranks patients according to hypo- and hyperglycemia risk for pharmacist intervention in two UF Health hospitals.

**Inpatient Psychiatric Facility Outcome and Process Measure Development and Maintenance**  
HHSM-500-2013-130071 [HHSM-500-T0004]  
Principal investigator: Kyle Campbell  
Principal investigator for UF subcontract: Almut Winterstein  
9/30/2014 – 9/29/2018 (\$2,006,320 – UF portion)  
This contract will support the development and validation of eight new performance measures for inpatient psychiatric facilities along with the maintenance of existing measures.

### Medication Therapy Management Support Training Services

Principal investigator: Richard Segal  
7/1/2017 – 9/30/2018 (\$336,099, Florida Department of Health)

This project creates patient care teams of Community Health Workers, or CHWs, and pharmacists to improve healthy behaviors among Native Americans, Blacks and Hispanics who have poorly controlled high blood pressure or diabetes mellitus.

### Identifying Medication Use Problems and Improving Minority Health through Community Health Workers

Principal investigator: Richard Segal  
7/1/2018 – 6/30/2019 (\$5,000, American Foundation for Pharmaceutical Education)  
This study evaluates the impact of a practice model that uses community health workers as pharmacist extenders in a federally qualified community health center in West Florida.

### Florida Minority Cancer Research and Training Center: Feasibility Studies

(00093359) P20CA192992  
Principal investigator: Folakemi Odedina  
Co-investigator: Richard Segal  
9/7/2017 – 4/30/2018 (\$158,966)  
Florida Minority Cancer Research and Training Center is the state's first and only National Cancer Institute P20-funded minority institution/cancer center partnership focused on cancer research and training for African-Americans.

### Application of Physiologically Based Pharmacokinetic Models to Inform Dosing Recommendations for Hormonal Contraceptives Coadministered with Other Medications

Principal investigator: Stephan Schmidt  
Principal investigator for subcontract: Joshua Brown  
3/1/2018 – 12/31/2020 (\$1,500,000, Bill & Melinda Gates Foundation)  
This project will develop pharmacological and pharmacoepidemiological evidence to inform treatment decisions for hormonal contraceptives and interacting medications by integrating real-world outcomes research, model-based meta analytic approaches and physiologically based pharmacokinetic modeling and simulations.

### Comparative Effectiveness of Direct-Acting Oral Anticoagulants (DOACs) in Nonvalvular Atrial Fibrillation (NVAf): Contrasting Methodological Approaches Using Real-World Data

Principal investigator: Joshua Brown  
9/1/2017 – 8/31/2018 (\$100,000, PhRMA Foundation)

## DRUG SAFETY SCIENTIST PUTS FACES TO HER GERIATRIC DRUG RESEARCH

Health data scientists consume copious numbers and figures, yet seldom meet the people their research benefits. But Yu-Jung “Jenny” Wei, Ph.D., a rising star in the field of drug safety, gets the chance to put faces to the numbers behind her antipsychotic drug research.

Thanks to a Career Development Award, or K award, sponsored by the National Institutes of Health’s National Institute on Aging, Wei interacts with patients as she shadows physicians at UF Health Family Medicine at Main and the Oak Hammock retirement community in Gainesville. The NIH award gives Wei, an assistant professor in the department of pharmaceutical outcomes and policy, research infrastructure and mentoring support designed to help young investigators become independent researchers.

“Shadowing in the practice helps me discover new problems and key issues of pain management in older adults, which could otherwise go unnoticed,” Wei said. “It allows me to understand the meaning behind the data, make sure the conclusions I am reaching are valid and outlines steps for my future research agenda.”

One of Wei’s current research areas is the study of antipsychotic medications, covering the complete age range from preschoolers to the elderly. Her K award focuses specifically on understanding how geriatric care and pain management are delivered in nursing homes — places that provide care for people with cognitive impairments.



Yu-Jung “Jenny” Wei, Ph.D., is using a Career Development Award to study pain management in older adults.

This project acknowledges the wide heterogeneity in methodological approaches in observational studies and seeks to evaluate the incremental differences each design approach may have on study results. As a case example, the study will aim to establish the comparative effectiveness and safety of DOACs in diverse patient populations.

### Novel Oral Anticoagulants and Adverse Drug Events - FDA

1U01FD005210-01

Principal investigator: Lawrence Lesko

Co-investigator: Joshua Brown

9/10/2014 — 8/31/2018 (\$1,500,000; Brown’s subaward is \$270,000)

This project integrates pharmacometrics and pharmacoepidemiology research to develop evidence regarding the need for stronger regulatory scrutiny of future generic products in this therapeutic area. By generating real-world evidence, these findings can inform the need for further pharmacometrics modeling or confirm findings from in silico models.

### Medicaid Prior Authorization Policies for Chronic Hepatitis C Treatment in Vulnerable Populations

K01DA045618

Principal investigator: Haesuk Park

5/1/2018 — 4/30/2023 (\$648,422)

This award supports the PI’s career development in viral hepatitis and health policy for individuals with substance use disorders and HIV coinfection.

### Clinical and Health Economic Outcomes of a Digital Health Offering in a Patient Population with Cardiovascular and Metabolic Chronic Diseases

Principal investigator: Haesuk Park

1/1/2017 — 6/30/2018 (\$68,625, Proteus Digital Health)

The purpose of this project is to evaluate the real-world impact of a digital medicine offering on adherence, clinical outcomes and health care utilization at Barton Health, a community hospital located in South Lake Tahoe in California.

### Using Machine Learning to Predict Problematic Opioid Use and Overdose

1R01DA044985

Consortium principal investigator: Wei-Hsuan “Jenny” Lo-Ciganic

9/2017 — 6/2020 (\$1,775,265)

The purpose of this study is to apply machine learning to develop two distinct prediction algorithms that can identify patients at high risk of problematic opioid use and overdose among Medicaid beneficiaries in Pennsylvania and Arizona.

### Using Machine Learning to Predict Opioid Overdose in Allegheny County

Principal investigator: Wei-Hsuan “Jenny” Lo-Ciganic

7/2018 — 6/2020 (\$61,819, Richard King Mellon Foundation)

The study will apply advanced analytics to develop prediction and risk stratification algorithms that can identify patients at high risk of opioid overdose in residents in Allegheny County in Pittsburgh.

## DR. HAESUK PARK RECEIVES GRANT TO EVALUATE IMPACT OF DIGITAL DEVICE THAT TRACKS DRUG ADHERENCE



Proteus Digital Health has awarded funding to Haesuk Park, Ph.D., an assistant professor in the department of pharmaceutical outcomes and policy, to study the effectiveness of a recently Food and Drug Administration-approved digital medicine, Abilify MyCite.

Abilify MyCite consists of an adhesive patch, a smartphone app and aripiprazole pills embedded with ingestible sensors. Once taken, the pill’s sensor signals the patch, which is worn on the patient’s abdomen, and sends information to the patient’s smartphone via Bluetooth. The patient can then choose to send the information to his or her doctor to track adherence.

The digital health solution is being pioneered with aripiprazole, which is used to treat schizophrenia and other mental illnesses, but Park hopes it can have an impact in other areas as well.

“We hope to see digital medicine help increase medication adherence and lower blood pressure and hemoglobin A1C, and, eventually, lead to improved health and economic outcomes in patients with cardiovascular and metabolic conditions,” Park said.

Park will use data from patients at Barton Health in California to evaluate the real-world impact of a digital health offering on adherence, clinical and economic outcomes, and health care utilization.



# RESEARCH AND GRADUATE FACULTY – AREAS OF INTEREST

## NEW FACULTY IN 2017-18



**KARAM DIABY, PH.D., M.SC.**  
**ASSISTANT PROFESSOR**

Diaby's research interests are in the field of economic evaluation, decision analytic modeling, health technology assessment and priority setting using multi-criteria decision analysis.



**WEI-HSUAN "JENNY" LO-CIGANIC, PH.D., M.S., M.S.PHARM.**  
**ASSISTANT PROFESSOR**

Lo-Ciganic's research program focuses on evaluation of treatment effectiveness and safety, application of advanced predictive analytics, and improvement of prescribing quality and health disparity, especially among vulnerable populations. Research interest areas include medication adherence, prescription drug abuse, treatment for substance use disorders, chronic disease management and oncology.



**SCOTT VOURI, PH.D., PHARM.D.**  
**ASSISTANT PROFESSOR**

Vouri's research interests include pharmacoepidemiology and pharmaceutical health services research related to the fields of inappropriate medication prescribing/deprescribing, geriatrics, urology and medication utilization following bariatric surgery.



**ALMUT WINTERSTEIN, R.PH., PH.D., FISPE**  
**DR. ROBERT AND BARBARA CRISAFI CHAIR AND PROFESSOR**  
Winterstein's research program focuses on the evaluation and prediction of drug safety and effectiveness in real-world populations and on devising ways to improve medication use. Clinical areas of interest include pediatrics and pregnancy, psychopharmacology and treatment and prevention of infectious disease.



**JOSH BROWN, PHARM.D., PH.D., M.S.**  
**ASSISTANT PROFESSOR AND ASSOCIATE GRADUATE PROGRAM DIRECTOR**  
Brown's research is in the field of comparative effectiveness and safety research focusing on anticoagulants, hematology and cardiology and in health care policy evaluation. His research also focuses on medication effects on mobility and aging in older adults and developing real-world evidence for generic drugs and biosimilars.



**ROBERT NAVARRO, PHARM.D.**  
**CLINICAL PROFESSOR**  
Navarro's research interests include real-world drug value assessments, performance-based risk-sharing arrangements with pharmaceutical manufacturers and value-based drug formulary management in various patient populations, as well as benefits and risks of public pharmaceutical policy on patient drug access, affordability and outcomes experiences.



**HAESUK PARK, PH.D.**  
**ASSISTANT PROFESSOR**  
Park's research program focuses on the evaluation of economic and health outcomes of medication and pharmaceutical care services, as well as policy associated with the use of pharmaceuticals.



**RICH SEGAL, R.PH., PH.D., M.S.**  
**PROFESSOR AND GRADUATE PROGRAM DIRECTOR**  
Segal's research focuses on improving the quality and safety of the medicine use process, with a particular emphasis on improving prescribing practices and creating collaborative practice models to improve medication use by patients.



**YU-JUNG "JENNY" WEI, PH.D.**  
**ASSISTANT PROFESSOR**  
Wei's research programs focus on questions surrounding the effectiveness, safety and quality of medication use in elderly patients with chronic conditions, especially those in nursing home settings.



## AWARDS & APPOINTMENTS



**YU-JUNG "JENNY" WEI, PH.D.**  
ASSISTANT PROFESSOR

- The UF Pepper Center Junior Scholar, NIH/NIA Claude D. Pepper Older Americans Independence Center, 2017
- Excellence Award for Assistant Professors, University of Florida, 2018
- Ad-hoc Member, NIH/NIDA Study Section (Special Emphasis Panel), 2018
- Ad-hoc Member, NIH/NIA Study Section (Special Emphasis Panel), 2018



**ALMUT WINTERSTEIN, R.PH., PH.D., FISPE**  
DR. ROBERT AND BARBARA CRISAFI CHAIR AND PROFESSOR

- Research Foundation Professorship, University of Florida
- Doctoral Dissertation Advisor/Mentoring Award, University of Florida
- Outstanding Clinical Science Research Award, for best paper in pharmaceutical clinical sciences, UF College of Pharmacy
- President elect, International Society of Pharmacoepidemiology
- Research advisory board member, American Society of Health-Systems Pharmacists Research Foundation
- Vice chair, Florida Medical Marijuana Research and Education Board
- Chair, FDA/CDER Drug Safety and Risk Management Advisory Committee



**KARAM DIABY, PH.D., M.SC.**  
ASSISTANT PROFESSOR

- Guest editor for PLoS One
- Editorial advisory board for Pharmacoeconomics — open, 2017-2020
- Grant reviewer for the Health Research Council of New Zealand, 2018
- Grant reviewer for the Academy of Medical Sciences in the United Kingdom, 2018



**JOSH BROWN, PHARM.D., PH.D., M.S.**  
ASSISTANT PROFESSOR AND ASSOCIATE GRADUATE PROGRAM DIRECTOR

- Editorial Advisory Board of the Journal for Managed Care and Specialty Pharmacy, or JMCP
- TEDMED Research Scholar 2017/2018
- Ad hoc reviewer for AHRQ Healthcare Safety and Quality Improvement Research Section
- Young Investigator Award, International Society for Thrombosis and Haemostasis, 2017
- Claude D. Pepper Junior Scholars Program, University of Florida Institute on Aging, 2017
- Entrepreneurship Faculty Fellow, Entrepreneurship & Innovation Center, Warrington College of Business, University of Florida, 2017

# FAST FACTS FOR 2018

**29**  
FACULTY AWARDS

**\$7M**  
IN EXTRAMURAL FUNDING

**\$3M**  
LED BY DEPARTMENT  
FACULTY

**1**  
BOOK

**72**  
PEER-REVIEWED  
MANUSCRIPTS





## DR. JOSH BROWN NAMED TEDMED 2018 RESEARCH SCHOLAR

For the second consecutive year, Joshua Brown, Pharm.D., Ph.D., M.S., an assistant professor of pharmaceutical outcomes and policy, was selected as a TEDMED Research Scholar. He is one of 45 scholars selected by TEDMED to help identify the topics, themes and speakers who appeared at TEDMED 2018 in Palm Springs, California. As a Research Scholar, Brown evaluated nominations and helped select TEDMED speakers who represent high-quality and scientifically credible ideas in health and medicine.

TEDMED annually selects a diverse group of individuals who are passionate about the future of health and medicine to serve as Research Scholars. Brown joined the College of Pharmacy's department of pharmaceutical outcomes and policy in November 2016, and his research interests include pharmacoepidemiology, drug policy and health outcomes.

## DR. WINTERSTEIN INSTALLED AS PRESIDENT-ELECT OF THE INTERNATIONAL SOCIETY FOR PHARMACOEPIDEMIOLOGY

The International Society for Pharmacoepidemiology installed Almut Winterstein, Ph.D., as president-elect on Aug. 25, at the ISPE Annual Conference in Prague.

As president-elect, Winterstein will serve on the executive board and chair the strategic planning committee. The committee will develop a new strategic plan and oversee a grant program that funds manuscripts relevant to ISPE's mission. She will take over as president of the organization at ISPE's 2019 Annual Meeting in Philadelphia.

Winterstein, a professor and the Dr. Robert and Barbara Crisafi Chair of Pharmaceutical Outcomes and Policy in the UF College of Pharmacy, joined ISPE in 2000 and has held numerous leadership roles during the past two decades. She has served on the ISPE education committee since 2008. In 2011-12, she chaired the academic council and was a member of the board of directors from 2014-17. Twice, she has served on scientific programming committees for ISPE meetings.

ISPE is dedicated to advancing the health of the public by providing a global forum for the open exchange of scientific information and for the development of policy, education and advocacy for the field of pharmacoepidemiology, including such areas as pharmacovigilance, drug utilization research, comparative effectiveness review and therapeutic risk management.

ISPE members represent the various scientific disciplines involved in studying drugs. Members are employed by the pharmaceutical industry, academic institutions, government agencies, nonprofit and for-profit private organizations.

Members have degrees in a number of fields, including epidemiology, biostatistics, medicine, nursing, pharmacology, pharmacy, law, health economics and journalism. With members in 53 countries, ISPE provides an international forum for sharing knowledge and scientific approaches to foster the science of pharmacoepidemiology.





# PUBLICATIONS

TRANSLATING BIG DATA INTO EVEN BIGGER,  
HEALTHIER AND SAFER OUTCOMES

1. Wei YJ, Zhu Y, Liu X, Bussing R, and Winterstein AG. 2018. Chronic concomitant use of stimulants and opioids in adults with attention deficit/hyperactivity disorder. *JAMA Network Open*. In press.
2. Alrwisan A, Antonelli PJ, Brumback BA, Wei YJ, and Winterstein AG. 2018. Azithromycin and sensorineural hearing loss in adults: A retrospective cohort study. *Otology and Neurotology*. In press.
3. Wei YJ, Simoni-Wastila L, Albrecht JS, Huang TY, Moyo P, Khokhar B, Harris I, Langenberg P, Netzer G, and Lehmann SW. 2018. Treated comorbid depression and COPD maintenance medication use and adherence in a Medicare population. *International Journal of Geriatric Psychiatry*. 33(2): e212-e220.
4. Albrecht JS, Khokhar B, Huang TY, Wei YJ, Harris I, Moyo P, Hur P, Lehmann SW, Netzer G, Simoni-Wastila L. Adherence and health care utilization among older adults with COPD and depression. *Respir Med*. 2017 Aug;129:53-58.
5. Wei YJ, Simoni-Wastila L, Lucas JA, Brandt N. Fall and fracture risk in nursing home residents with moderate-to-severe behavioral symptoms of Alzheimer's disease and related dementias initiating antidepressants or antipsychotics. *J Gerontol A Biol Sci Med Sci*. 2017 May 1;72(5):695-702.
6. Wei YJ, Liu X, Rao N, McPherson M, Jones MB, Bussing R, and Winterstein AG. 2017. Physical health outcomes in preschoolers with prior authorization for antipsychotics. *The Journal of Child and Adolescent Psychopharmacology*. 27(9): 833-839.
7. Xiao H, Jiang X, Chen C, Montero A, Diaby V. 2018. Longitudinal effects of adjuvant endocrine therapy on the quality of life in women with non-metastatic breast cancer. *Pharmacoecon Open*.
8. Chen, M, Goodin A, Xiao H, Han Q, Raissi D, Brown J. 2018. Hospitalization metrics associated with hospital-level variation in inferior vena cava filter utilization for patients with venous thromboembolism in the United States: Implications for quality of care. *Vasc Med*.
9. Jiang, Xinyi, Xiao, Hong, Segal, Richard, Mobley, William Cary, and Park, Haesuk. 2018. Trends in readmission rates, hospital charges, and mortality for patients with chronic obstruction pulmonary disease (COPD) in Florida from 2009 to 2014. *Clinical Therapeutics*.
10. Goodin A, Chen M, Raissi D, Han Q, Xiao H, and Brown J. 2018. Patient and hospital characteristics predictive of inferior vena cava filter usage in venous thromboembolism patients: A study from the 2013 to 2014 Nationwide Readmissions Database. *Medicine (Baltimore)*. 97(12): e0149.
11. Xiao H, Ali A, Tan F, Adunlin G, and Huang Y. 2017. Survival analysis of women with triple negative breast cancer using EMR-linked cancer registry data in Florida. *J Womens Health Gyn*. 1: 1-10.
12. Tan, Fei, Xiao, Hong, Gummadi, Sriharsha, Koniaris, Leonidas, Feldman, Jason, Ali, Askal, Adunlin, George, and Huang, Youjie. 2017. Impact of body mass index on prognosis for breast cancer patients. *Journal of Women's Health and Gynecology*. 4: 1-11.
13. Ali A, Xiao H, Tawk R, Campbell E, Semykina A, Montero A, and Diaby V. 2017. Comparison of health utility weights among elderly patients receiving breast-conserving surgery plus hormonal therapy with or without radiotherapy. *Curr Med Res Opin*. 33(2): 391-400.
14. Soria-Saucedo R, Liu X, Hincapie-Castillo J, Zambrano D, Bussing R, Winterstein AG. Prevalence, time trends and utilization patterns of psychotropic polypharmacy: Evidence from children and adolescent Medicaid beneficiaries, 1999-2010. *Psychiatric Services*. In press.
15. Wei, L, Antonelli, PJ, Dahm, P, Gerhard, T, Delayne, JAC, Segal, R, Crystal, S, and Winterstein, AG. 2018. Risk of sudden sensorineural hearing loss in adults using phosphodiesterase type 5 inhibitors: population-based cohort study. *Pharmacoecon Drug Safety*. In Press
16. Xu, D, Daniels, M, and Winterstein, AG. 2018. A bayesian nonparametric approach to causal interference on quantiles. *Biometrics*. In Press
17. Liu, X, Carney, PR, Bussing, R, Segal, R, Cottler, LB, and Winterstein, AG. 2018. Stimulants do not increase the risk of seizure-related hospitalizations in children with epilepsy. *J Child Adolesc Psychopharm*. 28(2): 111-116.
18. Choi, YY, Staley, B, Henriksen, C, Xu, D, Lipori, G, Brumback, B, and Winterstein, AG. 2018. A dynamic risk model for inpatient falls. *Am J Health Sys Pharm*. In Press.

## UF HEALTH STUDY LINKS COMMONLY PRESCRIBED EAR DROPS TO PERFORATED EARDRUMS

Use of commonly prescribed antibiotic ear drops may increase the risk of a perforated eardrum after ear tube surgery, according to a study by researchers at University of Florida Health.

The study, published in the journal *Clinical Infectious Diseases*, compares the rates of eardrum perforations after use of two commonly used ear drops, quinolones and neomycin, following an ear tube surgery.

Researchers from the UF colleges of Pharmacy and Medicine analyzed insurance data of nearly 100,000 children to identify eardrum perforations that require a costly surgical repair called tympanoplasty.

UF researchers found that children receiving quinolone ear drops are 60 percent more likely to have eardrum perforations compared with children receiving neomycin ear drops. In addition, the study suggests that using quinolones together with steroids might further raise the risk of eardrum perforations.

"We have tended to use quinolone ear drops fairly liberally after tympanostomy tube surgery," said Patrick Antonelli, M.D., a professor and chair of UF's department of otolaryngology and co-author of the study. "This was largely based on their relative lack of toxicity to the inner ear. Our findings suggest the need for more caution with the use of quinolone ear drops."

In recent years, quinolones have been under scrutiny because of their adverse effects on soft tissues and other issues. An advisory committee for the U.S. Food and Drug Administration concluded in 2016 that the benefit of quinolones in certain instances might not outweigh the risks with their use. The committee also highlighted the need for understanding the safety of topical applications of quinolones on soft tissues, such as the ear.

The UF researchers acknowledge that their study only demonstrates an association and doesn't definitively prove that quinolone ear drops cause persistent perforation of the eardrum. Nonetheless, the researchers said the findings raise a concern.

"Evidence on quinolones' detrimental effects on soft tissues, animal studies, clinical trials and observational studies overwhelmingly point to the possibility that quinolones could contribute to the development of persistent eardrum perforations," said Almut Winterstein, Ph.D., a professor and chair of the department of pharmaceutical outcomes and policy in the UF College of Pharmacy and co-author of the study.



# RISK-SHARING CONTRACTS COULD REDUCE U.S. DRUG PRICES

Public outrage over rising drug prices is leading pharmaceutical manufacturers, health insurers and patients to join forces in sharing the financial risks involved with unproven, expensive new medications.

University of Florida College of Pharmacy researchers found performance-based risk-sharing arrangements between pharmaceutical manufacturers and health insurance providers are common in Europe and predict they are likely to become more popular in the United States. These contracts help pharmaceutical manufacturers share the financial risks associated with new drugs when marketed after FDA approval. Manufacturers benefit from gaining sales and collecting outcome data available for newly approved pharmaceuticals. Health plans benefit by only paying for successful drug outcomes, and patients benefit by gaining earlier access to new drugs with potentially lower copays.

“The impact of these risk-sharing arrangements is that drug companies share financial risks with plans and patients, and the contracts help plans make value-based drug coverage decisions,” said Robert Navarro, Pharm.D., a clinical professor of pharmaceutical outcomes and policy at the UF College of Pharmacy, part of UF Health. “While drug prices may increase, these shared-risk contracts help reduce the net cost of providing expensive new drugs to patients.”

Navarro and colleagues recently published two research studies in the *Journal of Managed Care and Specialty Pharmacy* that examined perceptions and barriers of performance-based risk sharing arrangements, including outcomes-based contracting experiences. These practices link net drug cost for expensive pharmaceutical products to patient outcomes. Health insurance providers will pay for drug successes, but manufacturers refund some of the costs of drugs that fail to achieve specified outcomes.

UF College of Pharmacy researchers found that successful arrangements occur when manufacturers and insurers agree upon common performance metrics for measuring drug outcomes associated with many high-cost medical conditions. Diseases with subjective outcomes measurements or outcomes where data are difficult to obtain may not be candidates for such arrangements. In addition, drafting arrangements is complicated, which is why researchers identified a need for developing standardized contract templates.



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# UF STUDY RAISES QUESTIONS ABOUT OVERMEDICATING YOUNG CHILDREN DIAGNOSED WITH ADHD

A University of Florida study is among the first to evaluate whether a child’s age at the time of an attention deficit hyperactivity disorder diagnosis influences treatment and raises numerous questions about why young children with ADHD are being heavily medicated.

Researchers in the UF College of Pharmacy determined that a child’s age when diagnosed with ADHD may be a strong predictor of the types and number of medications that are later prescribed to treat psychiatric conditions.

“There is a significant amount of ADHD drug treatment happening at a young age that is not supported by evidence,” said Almut Winterstein, Ph.D., a professor and the Dr. Robert and Barbara Crisafi Chair in Pharmaceutical Outcomes and Policy. “In many instances, we do not know the impact these drugs have on the developing brain and whether any physical side effects may happen.”

Published in the *Journal of Clinical Psychiatry*, the study found that preschoolers with ADHD were more likely to receive antipsychotics, anticonvulsants and multiple mental health drugs during a five-year follow-up period compared with children with later-onset ADHD. The probability of a 3-year-old diagnosed with ADHD ending up on three mental health drug classes at the age of 8 was about 40 percent. In contrast, an 8-year-old’s probability of being on three drug classes when diagnosed with ADHD at age 8 was less than 10 percent and only increased about 13 percent by age 13.

For children diagnosed with ADHD between ages 3 and 9, each year of follow-up increased the probability of taking multiple mental health drugs and antipsychotic and anticonvulsant use, with the most profound effect in children diagnosed at age 3. In contrast, children diagnosed after age 9 showed no significant growth in any of the three outcomes over time.

American Academy of Pediatrics guidelines state that behavioral therapy is the recommended first-line treatment for ADHD in young children and should be tried before medication is prescribed.

The role of behavioral therapy in a treatment plan is one of a host of questions raised by the findings. UF researchers point out the treatment regimens, and the rationale for such clinical decisions, do not make a lot of sense. For instance, why did 40 percent of patients in the study diagnosed with only ADHD receive a triple combination of drugs, when two of the drug classes have no evidence of effectively treating ADHD?

“This study raises a lot of questions,” Winterstein said. “What is driving the treatment of young children, who seem to only have ADHD, with so many mental health drugs is a very important clinical research question that needs to be understood.”

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# LETTER FROM THE GRADUATE DIRECTOR

As the department’s graduate director, I am delighted to share information about the state of our graduate program. Our program is all about creating world-class researchers and policymakers in an interdisciplinary, collaborative environment. We have been laser-focused on preparing the next generation of independent, intellectual leaders in fields spanning academia, industry and regulatory science. Our graduate program offerings consist of M.S. degrees or a Ph.D. Our M.S. degree programs include a research-focused M.S. with a thesis program on campus and an applied non-thesis M.S. degree that can be completed online. During the past academic year, more than 30 graduate students have been part of our residential graduate program, with almost all working on a doctoral degree. These students choose a specialization area, which includes pharmacoepidemiology and safety sciences, pharmacoeconomics and outcomes research, or pharmaceutical health services research.

During the past year, these students first-authored more than 25 papers in peer-reviewed journals, including papers published in high impact journals such as Annals of Internal Medicine and Clinical Infectious Disease. Our students have traveled extensively to speak about their research, giving more than 50 presentations at national or international research or professional meetings. Among the many awards and honors presented to our students was an American Association of University Women fellowship and the International Society for Pharmacoepidemiology second-best student abstract award. Further, recent graduates have found incredible positions upon finishing their degree program, such as an associate director position at Merck and a postdoctoral fellowship at Harvard.

The online M.S. program, and related graduate certificate programs, have offered state-of-the-art learning experiences to more than 130 students in the past year. The specialty tracks in applied pharmacoeconomics, managed care pharmacy systems, patient safety in medication use and pharmaceutical regulation offer coursework tailored for working professionals. Students have raved about the value added from their participation in the program, and I encourage you to check out some of the student testimonials about how the program has impacted them professionally.

As you can tell, we are really proud of our students and graduates. They have accomplished a great deal during the past year and, most importantly, are making significant impacts on society through their research and their professional achievements.



**RICH SEGAL, R.PH., PH.D., M.S.**  
Professor and Graduate Director  
Associate Dean for Faculty Affairs

# WHO WE ARE

10  
FACULTY

2  
POSTDOCTORAL  
FELLOWS

4  
STAFF

30  
PH.D. STUDENTS

3  
RESIDENTIAL MASTER’S  
STUDENTS



## AS COMPETITION GOES DOWN, GENERIC DRUG PRICES RISE, STUDY FINDS

If the cost of your generic prescription drug has risen, it may be due to a lack of competition among drug manufacturers, according to a University of Florida College of Pharmacy study.

More than four in five prescriptions filled in the U.S. are for generic drugs, and UF researchers have found that market competition levels are strongly associated with generic drug price increases. Market competition levels are defined by the number of manufacturers producing a generic drug.

“The U.S. health care system has recently witnessed a relatively new phenomenon where prices for some older generic drugs have increased hundreds — even thousands — of percentage points in a short timespan,” said Chintan Dave, Pharm.D., Ph.D., the lead author of the study and a graduate of the UF College of Pharmacy’s department of pharmaceutical outcomes and policy. “There is a lot of speculation that these increases are due to drug shortages or industry consolidation, but without looking through a lens of scientific rigor, you cannot make these assumptions.

“This is one of the first studies that has linked market competition levels to generic drug prices for a large cohort of generic drugs,” he said.

In the study, published in the *Annals of Internal Medicine*, UF researchers analyzed 1.08 billion prescription drug claims from 2008-13 and examined 1,120 generic drugs. Using the Herfindahl-Hirschman Index, or HHI, a commonly accepted measure of market competition, researchers estimated competition levels for each drug. HHI values were calculated using a formula that takes into account a manufacturer’s market share.

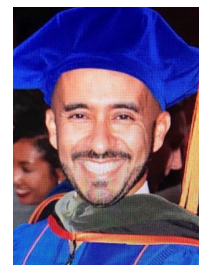
Nearly half the generic drugs studied were found to have competition levels resembling a duopoly — a competition level where only two manufacturers produce a drug. After controlling for other factors, a generic drug in the highest marketing competition group was expected to see a decrease of 32 percent in price over the study period, while a generic drug in the lowest market competition was expected to see a price increase of 47 percent over the same period. In addition, researchers found low market competition levels have a more pronounced correlation with drug prices in lower-priced generic drugs compared with their higher-priced counterparts.

“The connection this study establishes between market competition levels and generic drug prices should be an eye-opener for regulators responsible for the generic drug market,” Dave said. “In recent years, some generic manufacturers have sought to consolidate their market power by merging with rivals, but these mergers risk decreasing competition levels in parts of an already uncompetitive U.S. generic drug market.”



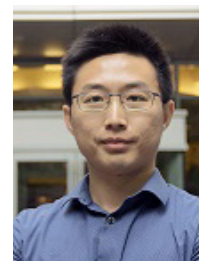
## TRAINING THE NEXT GENERATION OF SCIENTISTS

### 2018 GRADUATES



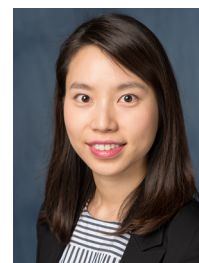
#### ADEL ALRWISAN, PH.D.

Dissertation: “Azithromycin: An Evaluation of Use and Safety”  
Advisor: Almut Winterstein  
First position after graduation: Consultant, Pharmacovigilance Department, Saudi Arabia Food and Drug Authority



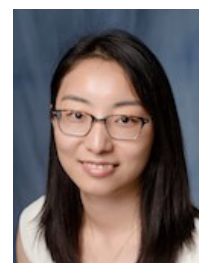
#### CHAO CHEN, PH.D.

Dissertation: “Observational studies in inflammatory bowel disease”  
Advisor: Abraham Hartzema  
First position after graduation: Epidemiologist, Takeda



#### YOONYOUNG CHOI, PH.D.

Dissertation: “Calibration of chronic lung disease severity as a risk factor for respiratory syncytial virus hospitalizations merging multiple data sources”  
Advisor: Almut Winterstein  
First position after graduation: Associate Director, Outcomes Research, Merck



#### YANMIN ZHU, PH.D., B.S.

Dissertation: “Metabolic Effects of Atypical Antipsychotic Use During Pregnancy”  
Advisor: Almut Winterstein  
First position after graduation: Postdoctoral Fellow, Division of Pharmacoepidemiology and Pharmacoeconomics, Harvard Medical School



# TRAINING THE NEXT GENERATION OF SCIENTISTS

## PH.D. STUDENTS



\*Abdullah Alalwan, Pharm.D.



Yasser Albogami,  
B.S.Pharm., M.S.



Hussain Alqhtani, B.S.Pharm.



Fatimah Alyani, M.S., B.Pharm.



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B.S.Pharm.



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Pharm.D., M.S.



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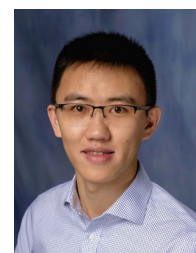


Motomori Lewis, B.S.

\* Graduated with a Ph.D. in December 2018

# TRAINING THE NEXT GENERATION OF SCIENTISTS

## PH.D. STUDENTS



Yan Li, B.S.Pharm., M.S.



\*Monica Munoz, Pharm.D., M.S.



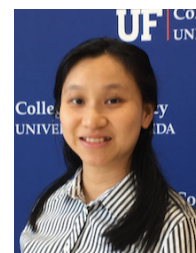
Phuong Pham, MSPH, B.S.Pharm.



Munaza Riaz, Pharm.D., M.Phil.



Amir Sarayani, Pharm.D., M.P.H.



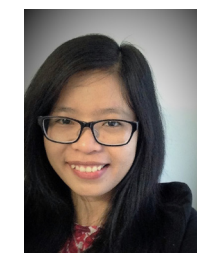
Yun Shen, M.P.H.



Steve Smith, Pharm.D., M.P.H.



Patrick Squires, Pharm.D.



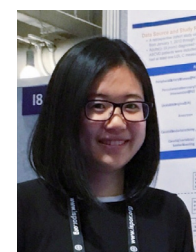
Thuy Thai, M.S. P.H., B.S.Pharm.



Phuong Tan Tran, B.S.Pharm., M.P.H.



Wei "Vivian" Wang,  
B.S.Pharm.



Xi Wang, M.P.H., B.M.



Sascha Wegmann, B.S.Pharm.



Bingcao "Glenn" Wu, M.S.

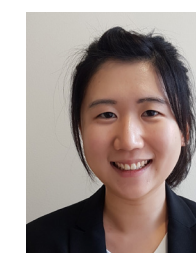
## THESIS M.S. STUDENTS



Mashael Alaskar, B.S.Pharm.



Abdulrahman Alsuhibani,  
B.S.Pharm.



Ching-Yu "Jessie" Wang,  
B.S.Pharm.



# ONLINE GRADUATE PROGRAMS

The department of pharmaceutical outcomes and policy's graduate programs include graduate certificates and training toward a non-thesis M.S. degree in four specialty tracks.

## APPLIED PHARMACOECONOMICS

Applied pharmacoeconomics centers on the conversion of pharmacoeconomic principles, methods and theories into practice to assess the value of pharmaceutical products and services used in real-world settings. Pharmacoeconomic studies provide scientifically grounded data to inform the optimal allocation of health care resources.

TRACK DIRECTOR: Karam Diaby, Ph.D., M.SC.

## MANAGED CARE PHARMACY SYSTEMS

Managed care implies a defined structure and process of designing and delivering covered health care benefits that include risk-sharing, outcomes measurement, price and utilization controls and quality assurance.

TRACK DIRECTOR: Robert Navarro, Pharm.D.

## PATIENT SAFETY IN MEDICATION USE

This track focuses on the design and evaluation of quality improvement initiatives aimed at reducing medication errors and adverse drug events. Intended primarily for pharmacists and other clinicians familiar with the drug use system, the curriculum is designed to focus on competencies and skills needed by those acting as patient or medication safety officers or working in quality divisions in health systems or clinical operations.

TRACK DIRECTOR: Randy Hatton, Pharm.D.

## PHARMACEUTICAL REGULATION

The curriculum in the pharmaceutical regulation track is designed to give students a firm grounding in the regulatory framework around the manufacturing, distribution, dispensing and use of pharmaceutical products, and to place pharmaceuticals in a large context of health care.

TRACK DIRECTOR: W. Thomas Smith, Pharm.D., J.D.

## FAST FACTS FOR 2018



**132**  
matriculated students



**46**  
Certificates awarded



**27**  
faculty taught courses



**36**  
M.S. graduates

# WE TRANSLATE BIG DATA INTO EVEN BIGGER, HEALTHIER and SAFER OUTCOMES

It's no secret drugs can do amazing, positive things for your health. But real-life medical miracles can turn into health threats. Many drugs have raised serious safety concerns after FDA approval, often because they were tested on only small samples or patients different than you.

At the University of Florida College of Pharmacy, we are working hard to gather and translate millions of real-life results into effective knowledge that can catch harmful side effects before they hurt you or your family. For us, this isn't just a numbers game. It's an opportunity to combine comprehensive data and proven expertise into a whole new way for pharmacists to improve and save patients' lives.

To learn more about how you can invest in our efforts to make drugs safer for you and your loved ones, please contact Elizabeth Zipper at [ezipper@cop.ufl.edu](mailto:ezipper@cop.ufl.edu) or 352-273-6605.

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