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Dear Candidates,

Thank you for your interest in the prestigious Regulatory Pharmaceutical Fellowship Program. We are proud to offer the only fellowship training program for pharmacists in partnership with the Food and Drug Administration.

Our fellows are immersed in specialized pharmacy practice in three diverse settings: academia, government, and the pharmaceutical industry. These experiences are enriched by the unparalleled training and mentorship provided by our preceptors. In fact, many of our preceptors, myself included, are former fellows as well.

When you review our program’s rich history, you will see a 100% success rate of our graduates gaining employment in their specialized field. It is our privilege to observe the rewards of this program to our extraordinary fellows. We are truly honored to offer this unique opportunity to you.

We look forward to meeting you and the other outstanding applicants this year. Pharmacy is a small world made even smaller by our clinical specialties. No matter which direction you choose, we look forward to our paths crossing in the future.

Sincerely,
Lindsay E. Wagner, PharmD, BCPS
Lieutenant Commander, U.S. Public Health Service
The purpose of the Regulatory Pharmaceutical Fellowship program is to train selected candidates in one of three tracks focused on the medical and regulatory aspects of drug information dissemination, drug advertising and promotion, or medication safety. The program serves to maintain and enhance a scientific link among FDA, academia, and the pharmaceutical industry. The fellowship provides participants the unique opportunity to experience careers in the areas of government, academia, and industry, qualifying graduates to pursue career opportunities in each respective area.

**FELLOWSHIP BENEFITS**

- Competitive stipend
- Reimbursement for relocation during fellowship and professional travel expenses
- Enrollment in the Indiana Pharmacy Teaching Certificate (IPTeC) Program
- Vacation and University holidays
- Optional Purdue University benefits package (health, Rx, vision, and dental)
- 1-year membership in the Regulatory Affairs Professionals Society (RAPS) and a copy of Fundamentals of Regulatory Affairs

**2020 – 2022 Recruitment**

Drug Information – 3 positions
Medication Safety – 2 positions
1 position tentative
ELIGIBILITY REQUIREMENTS

The fellow must be a graduate from an ACPE-accredited college of pharmacy, or otherwise eligible for licensure as a pharmacist, prior to the start of the fellowship term. All applicants must be U.S. citizens to complete the program. Candidates who do not meet this requirement should not apply.

Preliminary interviews will be conducted during PPS at the American Society of Health-System Pharmacists (ASHP) Midyear Clinical Meeting annually. Save the date for on-site interviews on January 3, 2020.

APPLICATION PROCESS

All interested applicants must submit the following:

1. Letter of intent for one of the two tracks – specify track & sponsor of interest
2. Contact information for three references – including email and phone number
3. Curriculum Vitae
4. Official transcripts (electronic copies accepted)

All application materials should be submitted electronically to the email contacts below no later than 11:59 pm EST on Wednesday, December 4, 2019.

On-site interviews will take place at FDA in Silver Spring, MD on Friday, January 3, 2020. For more information, visit our website at: www.fda.gov/RegPharmFellowship

Submit to:
Drug Information Track
DrugInformationFellowship@gmail.com
Medication Safety Track
MedicationSafetyFellowship@gmail.com

Additional fellowship opportunities are available with our partners. Visit FDA’s ORISE website at: https://orise.orau.gov/fda/
or Purdue’s website at:
www.phpr.purdue.edu/residencies/current
## DRUG INFORMATION

### PROGRAM OVERVIEW

**INDUSTRY**
This experience provides the opportunity for the fellow to gain training as a member of a medical information team in the pharmaceutical industry. The fellow will develop skills related to development and delivery of drug information to healthcare professionals, payors, consumers, and business partners through a variety of methods.

See locations below.

**FDA**
The FDA experience provides an opportunity for fellows to refine their drug information skills in a regulatory setting. Fellows respond to drug information inquiries from patients, health care professionals, and regulated industry; create and disseminate content; and assist with a number of high-profile initiatives.

Silver Spring, MD

**ACADEMIA**
The Purdue University experience exposes the fellow to academia and an institutional-based drug information center at Indiana University Health. Fellows will conduct a research project for presentation at a national meeting and publication in a peer-reviewed pharmacy journal. Significant teaching experience in an out of the classroom is provided.

West Lafayette & Indianapolis, IN

### FELLOWSHIP SCHEDULE: 3 TRACKS, 1 FELLOW EACH

#### TRACK 1

<table>
<thead>
<tr>
<th>COLLEGE OF PHARMACY</th>
<th>DIVISION OF DRUG INFORMATION</th>
<th>GLOBAL MEDICAL INFORMATION</th>
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<tr>
<td><strong>6 months:</strong></td>
<td><strong>6 months:</strong></td>
<td><strong>12 months:</strong></td>
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#### TRACK 2

<table>
<thead>
<tr>
<th>COLLEGE OF PHARMACY</th>
<th>MEDICAL INFORMATION</th>
<th>DIVISION OF DRUG INFORMATION</th>
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<tbody>
<tr>
<td><strong>6 months:</strong></td>
<td><strong>12 months:</strong></td>
<td><strong>6 months:</strong></td>
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#### TRACK 3

<table>
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<tr>
<th>MEDICAL INFORMATION</th>
<th>DIVISION OF DRUG INFORMATION</th>
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<tr>
<td><strong>12 months:</strong></td>
<td><strong>6 months:</strong></td>
<td><strong>6 months:</strong></td>
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<tr>
<td>07/2020 – 06/2021</td>
<td>07/2021 – 01/2022</td>
<td>01/2022 – 07/2022</td>
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</table>
Kaitlin Montagano, PharmD
Industry Sponsor: Astellas Pharma US, Inc.
Second Year Fellow: 2018-2020 Cycle

Megan Cuomo, PharmD
Industry Sponsor: Janssen Scientific Affairs, LLC
Second Year Fellow: 2018-2020 Cycle

Minh Tran, PharmD
Industry Sponsor: Janssen Scientific Affairs, LLC
First Year Fellow: 2019-2021 Cycle

Dylan Vo, PharmD
Industry Sponsor: Eli Lilly and Company
First Year Fellow: 2019-2021 Cycle

CURRENT FELLOWS

PAST FELLOWS

2017-2019: Kiersten Rybakov, PharmD
Associate Consultant, Global Medical Information
Eli Lilly and Company

2017-2019 Jacqueline Wasynczuk, PharmD
Assistant Professor, Department of Pharmacy Practice
Thomas Jefferson University

2016-2018: Sandra Bai, PharmD
Pharmacist, Division of Drug Information
Food and Drug Administration

2015-2016: Megan N. Freeland, PharmD
Owner, Healthcare Digital Marketing Consultant
StockRose Creative, LLC

2014-2016: Jay R. Fajiculay, PharmD
Designated Federal Officer, Division of Advisory Committees and Consultant Management
Food and Drug Administration

2013-2015: Bhavani T. Parikh, PharmD
Leader, Global Medical Affairs
AstraZeneca

2012-2014: Andrea M. TenBarge, PharmD
Consultant, Medical Digital Strategy and Capabilities
Eli Lilly and Company

2011-2013: Genevieve Lynn (Ness) Engle, PharmD
Director, Christy Houston Foundation Drug Information Center
Assistant Professor of Pharmaceutical, Social and Administrative Sciences, Belmont University College of Pharmacy

2010-2012: Kimberly (Wu) Chiu, PharmD
Science Policy Analyst
Division of Clinical Outcome Assessment
Office of New Drugs- Immediate Office
Food and Drug Administration

2009-2011: Lindsay E. Wagner, PharmD, BCPS
Lieutenant Commander, U.S Public Health Service
Branch Chief, Division of Drug Information
Food and Drug Administration

2007-2009: Jean Cunningham, PharmD
Senior Clinical Content Specialist, Value-Based Care
IBM Watson Health

2005-2007: Sanjeev K. Bhanot, PharmD
Director of Medical Affairs
Merz Pharma Canada, LTD

2003-2005: Tanya Nelson, PharmD
Senior Medical Science Liaison
Janssen Scientific Affairs, LLC

2001-2003: John Ng, PharmD
Consumer Safety Officer, Division of Clinical Compliance Evaluation, Office of Scientific Investigations
Food and Drug Administration
**Why Drug Information?**

“The three rotations provided in this fellowship build on each other, allowing me to continue to refine my drug information and teaching skills over the course of the two years. I am also thankful for the excellent professional connections and mentors that I have gained from this program.”

- Megan Cuomo
Second Year Drug Information Fellow

“This fellowship program is unique in its provision of in-depth exposure to drug information practice within academia, government, and the pharmaceutical industry. Over a year in, the breadth of opportunities I have experienced has far surpassed the high expectations I had when I chose this program. I could not be more thankful to have had this opportunity.”

- Kaitlin J. Montagano
Second Year Drug Information Fellow

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**PROGRAM PRECEPTORS**

**Amy H. Sheehan, PharmD | Purdue University**
amheck@indiana.edu

For the past twenty years, Amy has worked with Purdue University College of Pharmacy and the Indiana University (IU) Health Center for Medication Management, where she contributes to the provision of comprehensive drug information services for all IU Health-affiliated hospitals. She has published over 40 peer reviewed articles in the pharmacy literature and authored book chapters for therapeutics and drug information textbooks. Amy serves on the Indiana Pharmacy Teaching Certificate (IPTeC) Program Executive Committee and is currently a member of the Editorial Board for the Annals of Pharmacotherapy and Currents in Pharmacy Teaching and Learning. She serves as course coordinator for a drug information and advance literature evaluation class, and is chair of the professional program curriculum committee.

**Lindsay Wagner, PharmD, BCPS | LCDR, USPHS | FDA**
Past Fellow 2009 - 2011 Cycle
Lindsay.Wagner@fda.hhs.gov

LCDR Wagner received her PharmD degree from the Albany College of Pharmacy and Health Sciences. She has been with the FDA in the Division of Drug Information since graduating from the fellowship. In her current role as Branch Chief, she supervises other pharmacists to help the public get the accurate, science-based information they need about human drugs. Lindsay provides leadership for many additional programs, including Expanded Access and social media, and precepts students.

**Sandra Bai, PharmD | FDA**
Past Fellow 2016 - 2018 Cycle
Sandra.Bai@fda.hhs.gov

Sandra earned her PharmD degree from Butler University College of Pharmacy. Following graduation, she completed the two year Regulatory Pharmaceutical Fellowship in Drug Information with rotations at Purdue University, Janssen Scientific Affairs, LLC, and FDA. Following the fellowship, she accepted a position with the Division of Drug Information (DDI) at FDA. In her current role at DDI, Sandra provides timely, complete, and accurate responses to inquiries from consumers, health care professionals, and industry. Sandra is also a member of DDI’s Social Media team and helps produce Drug Info Rounds videos.

**Raj Patel, PharmD | FDA**
Raj.Patel@fda.hhs.gov

Raj earned his PharmD degree from the University of Sciences in Philadelphia. In his current role at FDA, he is the Social Media Lead for FDA’s Center for Drug Evaluation and Research. He oversees the development and release of all information distributed via social media and provides expert advice and counsel on social media activities to engage stakeholders. Raj leads a team of pharmacists who provide drug information through social media to consumers, health care professionals, and industry. He is also a member of the DDI podcast team and helps produce three podcast series.
Why Drug Information?

"I chose this fellowship because of the unique opportunity to practice drug information in various settings and the illustrious history of prior fellows. I have learned so much during my first few months and am excited to continue to develop my drug information skills at my next rotation site."

-Dylan Vo
First Year Drug Information Fellow

"This fellowship has opened so many doors for me as a recent graduate. The individuals I have met and the opportunities that I’ve been given as a fellow far exceed my expectations. I cannot express my gratitude enough for my preceptors and co-fellows alike. There is no doubt in my mind that I will be prepared for whatever career opportunities I embark on in the future."

-Minh Tran
First Year Drug Information Fellow
MEDICATION SAFETY

PROGRAM OBJECTIVES

ACADEMIA
- Gain exposure to academia and the various medication safety initiatives
- Actively participate in practice-based research to foster the discovery and delivery of information and practices to enhance medication safety
- Unique opportunities, such as publishing original research, delivering presentations, and teaching

West Lafayette & Indianapolis, IN

INDUSTRY
- Actively contribute to the Surveillance team within Global Patient Safety
- Engage cross-functionally between pre- and post-marketed compounds to detect and evaluate adverse events to determine if they are drug-related
- Gain experience in safety signal detection and evaluation as well as the development of regulatory documents

See locations below.

FDA
- Actively contribute to and learn about the work done in the Office of Surveillance and Epidemiology (OSE)
- Participate in intra- and inter-center projects in both the pre- and post-market arenas
- Utilize adverse drug event reporting data, medical literature, and established knowledge of marketed drug products to assess post market safety related issues.

Silver Spring, MD

FELLOWSHIP SCHEDULE: 2 TRACKS, 1 FELLOW EACH

TRACK 1
* Track 1 is currently TENTATIVE and subject to change.

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<tr>
<th>COLLEGES OF PHARMACY</th>
<th>GLOBAL PATIENT SAFETY</th>
<th>OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY</th>
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TRACK 2

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<tr>
<th>COLLEGES OF PHARMACY</th>
<th>GLOBAL PATIENT SAFETY</th>
<th>OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY</th>
</tr>
</thead>
</table>
Danya Faruqi, PharmD  
Industry Sponsor: Eli Lilly and Company  
Second Year Fellow: 2018-2020 Cycle

Jonell Nwabueze, PharmD  
Industry Sponsor: Eli Lilly and Company  
First Year Fellow: 2019-2021 Cycle

Charlotte Moureaud, PharmD  
Industry Sponsor: Abbvie  
First Year Fellow: 2019-2021 Cycle

Why Medication Safety?

"Let’s say you have the best drug on the market, cures the disease 100% of the time, favorable dosing, and is even affordable. There’s one thing that will stop you from approving your drug. No matter how effective your miracle compound is, you have to answer one question: is your drug safe?"

The drug development process will continue to evolve, but the foundational piece, medication safety, will stand the test of time. Here’s a good question: What job do you want for the rest of your life? Here’s an even better question: Will you have the skillset and training to enter a different role if you change your mind?

From the academic component at a top university, to a built-in high-level industry experience, followed by unparalleled training at the FDA, this fellowship provides an abundance of exclusive experiences. After taking a look at the diverse current roles of our past fellows, I knew I would have the opportunity to work in many different sectors post-fellowship. I chose medication safety aware that no matter what project I work on, or the stage in development a product is in: one thing will remain constant and non-negotiable: the safety of that compound. This fellowship gives me the tools to create an impenetrable foundation with transferable skills that will carry me throughout my career. I chose this fellowship after deciding the foundation of my career is also non-negotiable."

- Jonell Nwabueze  
First Year Medication Safety Fellow
Why Medication Safety?

“Medication safety has been a passion of mine for quite some time. This fellowship will allow me to expand my knowledge and expertise in several different settings, impacting patient lives on a global scale.”

-Charlotte Moureaud
First Year Medication Safety Fellow
**Program Preceptors**

**John B. Hertig, PharmD, MS, CPPS, FASHP | Butler University**  
jhertig@butler.edu  
John B. Hertig is an Associate Professor and Vice-Chair of Pharmacy Practice at Butler University where he specializes in management, entrepreneurship, and patient safety. He received his Bachelor of Science in Pharmaceutical Sciences and Doctor of Pharmacy degrees from Purdue University. He completed a PGY1 & PGY2 health-system pharmacy administration residency at The Ohio State University Medical Center while obtaining his Master’s degree. Among various national and international appointments, he serves as Vice President of the Americas for the International Pharmaceutical Federation’s Hospital Section, and as a Director for the Alliance for Safe Online Pharmacies.

**Alissa Russ, PhD | Purdue University**  
aruss@purdue.edu  
Dr. Alissa L. Russ is Assistant Professor of Pharmacy Practice, Purdue University and Affiliate Investigator with Regenstrief Institute, Inc. in Indianapolis, IN. She teaches “Patient Safety and Informatics” to third-year pharmacy students. Dr. Russ integrates health services research with human factors engineering methods to improve the design of health information technologies (IT) for healthcare professionals and patients. Dr. Russ leads federally-funded research to evaluate the design of medication alerts, including drug-allergy, drug-drug interaction, and drug-disease alerts. Dr. Russ has given over thirty invited presentations and her research has received special recognition from the International Medical Informatics Association.

**Dan Degnan, PharmD, MS, CPPS, FASHP | Purdue University**  
ddegnan@purdue.edu  
Dan Degnan currently serves as the Associate Director for the Professional Program Laboratory and is a Clinical Assistant Professor of Pharmacy Practice (Courtesy) at the Purdue University College of Pharmacy. He has an appointment at the Regenstrief Center for Healthcare Engineering at Purdue as a Clinical Research Associate with expertise and research interests in the area of medication safety technology, advanced pharmacy automation, pharmacy operations and high reliability in healthcare. Prior to his role at Purdue, Dr. Degnan served as the Medication Safety Officer at Community Health Network in Indianapolis for almost 10 years. He has held leadership positions in national organizations for both pharmacy and healthcare quality.

**Kyle Hultgren, PharmD | Purdue University**  
khultgre@purdue.edu  
Kyle Hultgren is the director of the Purdue University College of Pharmacy’s Center for Medication Safety Advancement. Dr. Hultgren’s current research includes extensive work on dashboards and measurement systems for the evaluation and improvement of medication use systems as well as large adverse event data set analysis. He holds multiple copyrights on mobile computer simulation technology and two patents on medical devices designed to improve patient safety. Dr. Hultgren lectures nationally and internationally on safe medication use practices and teaches regularly in the Doctor of Pharmacy curriculum where he is the 2016 Dr. Aziz Teaching Award recipient.

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**Fellow Spotlight**

Danya completed her academic rotation with Purdue University and is currently at Eli Lilly and Company where she is working as a Clinical Surveillance Scientist within Global Patient Safety. Over the past 11 months, she has worked on completing deliverables for drugs in a variety of therapeutic areas including diabetes, psych, and oncology. For her final rotation, Danya will be rotating through the FDA within the Division of Pharmacovigilance and the Division of Medication Error Prevention and Analysis. Danya loves to travel and trying new foods. Being a Midwest girl, she is excited to explore the east coast one bite at a time!

-Danya Faruqi  
Second Year Medication Safety Fellow
ADVERTISING AND PROMOTION

PROGRAM OBJECTIVES

INDUSTRY
- Develop an understanding of FDA regulations and guidance, industry codes, and Federal and State laws as it relates to prescription drug advertising and promotional materials and activities
- Work directly with internal business partners such as marketing, legal, medical, and others to ensure that a broad range of promotional materials are in compliance with applicable regulations and internal policies

FDA
- Gain experience in the government promotional review process and provide overviews of the Federal Food, Drug, and Cosmetic Act and relevant FDA guidance documents
- Assist in the review of promotional materials, evaluate draft product labeling, research and evaluate industry complaints, and work with other functions in the Office of Prescription Drug Promotion (OPDP)

ACADEMIA
- Gain exposure to upper level academia and the different functions and responsibilities of academic administrators
- Gain significant teaching experience through provision of didactic education including coordination of a core PharmD management and marketing course and experiential training of students

FELLOWSHIP SCHEDULE: 1 TRACK, 1 FELLOW

<table>
<thead>
<tr>
<th>INDUSTRY ADVERTISING &amp; PROMOTION</th>
<th>OFFICE OF PRESCRIPTION DRUG PROMOTION</th>
<th>COLLEGE OF PHARMACY</th>
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<tr>
<td>9 months</td>
<td>9 months</td>
<td>6 months</td>
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PAST FELLOWS

2017-2019: Nikki Pedersen, PharmD
Senior Regulatory Affairs Specialist, Ad/Promo
Abbott Laboratories

2015-2017: John Riehl, PharmD
Associate Director
Regulatory Affairs, Advertising and Promotion
Allergan

2013-2015: Sam Davis, PharmD
Consultant, Global Regulatory Affairs
US Advertising & Promotion
Eli Lilly & Company, Lilly USA, LLC

2011-2013: Ankur Kalola, PharmD
Regulatory Review Officer
Office of Prescription Drug Promotion
U.S. Food and Drug Administration

2009-2011: Nital Patel, PharmD, MBA
Senior Medical Science Director, East Team Lead
Relypsa

2007-2009: Sheetal Patel, PharmD
Head, Regulatory Advertising and Promotion
Johnson & Johnson Health Care Compliance

2005-2007: Samuel Skariah, PharmD
Commander, U.S. Public Health Service
Team Leader, Office of Prescription Drug Promotion
U.S. Food and Drug Administration

2003-2005: Amit Patel, PharmD
Sr. Director, Regulatory Affairs Advertising and Promotion
ACADIA Pharmaceuticals Inc.
Sauers, president of the Office Company, to practice in regulatory affairs, has been engaged in the 10-year OPDP since 2005. Sauers served as the Supervisor of the Advertising and Promotion Policy Staff leading OPDP’s guidance, regulatory, and policy development, as well as the social science research, legal, and project management teams.

Sam Skariah, PharmD | CDR, USPHS | FDA
Past Fellow 2005 - 2007 Cycle
sam.skariah@fda.hhs.gov

C.D.R. Skariah graduated from the University of Illinois at Chicago College of Pharmacy where he received his PharmD. He then went on to complete this same track of the regulatory fellowship that was in conjunction with Purdue University, Eli Lilly and Company, and the FDA. He is a Commander in the United States Public Health Service and has served as Team Leader within FDA’s Office of Prescription Drug Promotion (OPDP) since 2013. Previous to that role, he served as an FDA-OPDP reviewer for various therapeutic areas.

Carrie Newcomer, PharmD | FDA
carrie.newcomer@fda.hhs.gov

Carrie graduated from the University of Pittsburgh School of Pharmacy where she received her PharmD. She has been a regulatory review officer for the Office of Prescription Drug Promotion (OPDP) since 2005, and currently reviews promotional materials for ophthalmology and transplant products. She also coordinates the new reviewer training program and the FDA Pharmacy Student Experiential Program for OPDP. During her time at OPDP, Carrie has been responsible for working in various therapeutic areas including reproductive, medical imaging, hematology, and urologic products.

Steven Abel, PharmD, FASHP | Purdue University
abels@purdue.edu

Prior to his appointment as associate provost for engagement in 2016, Steve served as associate vice president for engagement, associate vice provost for faculty affairs and held various positions within the Purdue University College of Pharmacy. He has 18 years of prior practice experience, primarily in a health-system setting. Steve received his B.S. (Pharmacy) and PharmD degrees from Purdue University and completed residency at Mayo Medical Center. Steve is passionate about student education, faculty/leadership development, mentorship and community engagement. Steve developed the only fully immersive USP 797 compliant virtual classroom used for student education, commercially marketed through his company, Penguin Innovations.

Why Advertising and Promotion?

“I love how Regulatory Advertising and Promotion is a field in which I can utilize my pharmacy knowledge to analyze clinical trials, as well as exercise my interpersonal skills to lead discussions among cross-functional groups. I became especially interested in this fellowship due to the unparalleled and invaluable opportunities it provides to gain significant work experience in both FDA and pharmaceutical industry. I am also highly anticipating the academia portion because I am excited to not only give back to the Purdue University College of Pharmacy, but also learn about mentorship and teaching, which is knowledge that will surely be applicable to any future career path. Throughout this fellowship, I am humbled I will have the privilege to work with preceptors who are not only invested in my personal and professional growth, but are also highly respected and experienced professionals in their respective fields. I am truly looking forward to making an impact on patient care by ensuring both patients and healthcare providers are appropriately educated about their medications through drug advertising and promotional materials.”

-Jennifer Chen
First Year Advertising and Promotion Fellow
REGULATORY PHARMACEUTICAL FELLOWSHIP

Government Industry Academia

2020-2022

To reach our current fellows and ask questions, write to:

Drug Information Track:
DrugInformationFellowship@gmail.com
Medication Safety Track:
MedicationSafetyFellowship@gmail.com
Advertising and Promotion Track:
DrugMarketingFellowship@gmail.com

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