This past year, we had a record-breaking 635 candidates apply to the Rutgers Pharmaceutical Industry Fellowship (RPIF) program at ASHP Midyear in Las Vegas, Nevada! We also welcomed two new partner companies into the RPIF family, Amgen, a biotechnology company on the West Coast, and McCann Health, a healthcare marketing and communication company on the East Coast.

Despite the potential logistical difficulties due to increased applicants, Midyear recruitment was a great success due to careful planning and collaboration. For example, the amazing efforts by the Technology Committee, supporting Fellows, partner companies, and several process changes enabled us to shorten the duration of interview scheduling by one hour compared to 2015.

Although Midyear 2016 ended only a few months prior, we on the Midyear Committee are already brainstorming how to improve the process for 2017 in Orlando, Florida! This year we are collecting feedback from stakeholders, Fellows, and candidates to identify areas of success, as well as areas of improvement for future years. As the fellowship environment continues to become more competitive, we will continue our efforts to improve the recruitment process.

The recruitment process of 2016 proved to be immensely successful, and on behalf of the Midyear Committee, we would especially like to thank Dean Barone, Dr. Toscani, as well as current and alumni fellowship classes for their continued support of the RPIF program.
PFIZER “PFIGHTS” BREAST CANCER
Medical Information: 
The Perfect Blend of Science with Passion
By: Richa Shah, Pharm.D.

Medical Information (MI) serves as one of the prominent customer facing groups within Pfizer Inc. One of the core functions of MI includes interacting with healthcare professionals (HCPs) and other customers to respond to unsolicited medical requests. As the role of MI has evolved, other responsibilities have been placed under the remit of MI, including supporting congresses, developing customized Standard Response Documents (SRDs), and reviewing medical and promotional material. The value of MI as an internal partner in the pharmaceutical industry is consistently demonstrated through cross-functional collaboration and delivering on the core functions.

Supporting Ibrance (palbociclib), the first in class CDK4/6 inhibitor agent approved in 2015 for metastatic breast cancer, has been a rewarding experience. It has allowed me to be at the forefront of transforming the landscape of HR+/HER2- metastatic breast cancer, as it rapidly evolves. While staffing the MI booth at the San Antonio Breast Cancer Symposium in December, I interacted with HCPs and other researchers invested in improving patient care. Supporting the MI booth was intimidating initially; however, as I engaged in scientific conversations and exchanged clinical data, it became a collaborative discussion that was driven by something I was familiar with – the science and passion for improving the lives of our patients. The experience of interacting with oncology HCPs from around the world reinforced the proven value of Ibrance in the metastatic breast cancer landscape, and how our contributions have impacted the lives of more than 46,000 patients in two years.

TEACHING COMMITTEE TEACHES TOGETHER
By: Tony Luu, Pharm.D., & Mary Hanna, Pharm.D.

The Teaching Committee, comprising of Tony Luu and Mary Hanna, taught their first class together at Rutgers University in January 2017! The class was Self Care with a focus that day of Diabetes. The primary objective was to observe any practical and/or logistical challenges that Fellows may undergo, so that Mary can advance this committee next year. We also taught with other RPIF Fellows, Brad Rzendzian and Maggie Gandhi.
FELLOW SPOTLIGHT: LAUREN CORRY, PHARM.D.  
First Year Medical Affairs Fellow at Acorda Therapeutics

The transition from pharmacy student to post-doctoral Fellow has its benefits and challenges. In addition to adjusting to a new career, many Fellows also balance several other commitments, while maintaining an ever important work-life balance. One such Fellow, Lauren Corry, is doing it all—an industry career, an athletic career, and a part-time job—while still making time for social events with friends and family. We sat down to talk with Lauren to chat more about her extracurricular activities and work outside of the fellowship program, and how she balances it during her first year at Acorda.

Many of us have hobbies or side jobs outside of our commitments to the fellowship. What do you spend your time doing when you’re not at the office?

When I’m not at work, I spend my time playing roller derby as a member of the #1 ranked team in the world, Gotham Girls Roller Derby, as well as recently being appointed to Team USA Roller Derby for the 2018 World Cup in England. I also have a second job coaching ice skating on the weekends. So, I spend all my time when I’m not at the office in skates, which is fulfilling for me because skating is my passion in all of its forms!

How much time do you dedicate to each of these activities?

On average, I spend about 10 hours a week (evenings and weekends) skating or working out. Since I am in a leadership position in the league, I also spend a couple hours a week planning or coaching practices for other skaters. I teach ice skating on Saturdays starting early in the morning with lessons going for about 7-8 hours.

How do you manage your time and prevent burnout with such a busy schedule?

I grew up competitively ice skating since the age of 6, fitting practice around a busy school schedule along with other interests. I think that at an early age I realized that for me, focusing on the task at hand and taking things one step at a time every day made me the most efficient. I also make sure to have at least a few hours of “down time” a week where I don’t schedule anything. Also, derby and ice skating both have high and low periods in the year which helps with balance. The summer and fall are more derby focused, whereas the winter and early spring are peak times for figure skating. Ultimately though, I love everything I do, so the excitement I have about these activities keeps me feeling driven and energizes me! I think that if you truly love something or are curious about it, there is a way to make time for it. You will always make time for things you really care about.

These interests seem so different from life in the office or the world of pharmacy! How do you connect the dots?

Something that translates really well through everything that I do is the importance of team work and achieving a common goal. In derby, work, and the ice rink, I collaborate with a very diverse set of people, and no matter where we come from, we are present together to achieve something. This can be really unifying when there are personality or stylistic clashes within a group. I have also been able to develop the ability to think more critically from derby, and have fostered a more active and direct communication style at work. Additionally, when I teach ice skating or coach derby, I am constantly translating my knowledge and expertise in different ways to cater to the skill level and maturity of my students. I think this is a particularly important skill to have while being in Medical Affairs, as I am always keeping in mind the audience of the letters I write or materials I work on, or how I am explaining something when working inter-departmentally. The way in which you communicate things is so important, and in both of my “extracurricular activities” I am challenged in new and different ways all of the time to communicate better!
The Organization Outreach Committee (OOC) has had an extremely successful year thus far sending Fellows to represent RPIF at various national, regional, and local conferences across the US.

This past fall, we participated in 22 OOC visits, 4 of them being entirely new organizations and were able to interact directly with over 500 students! As we kick-off the spring / summer season, we plan to continue the momentum by sending Fellows to participate in 8 conferences, with a strong focus on roundtable events, panel discussions, and seminars in order to ensure the highest value for the students we meet. Our biggest event of the year, APHA Annual, which will be held in San Francisco, California, is quickly approaching (March 24—26). Our OOC list of events are as follows for APHA Annual:

- **Rutgers Roundtable Session (1)**: 3/24/2017 @ 3:30—4:30 PM PST
- **Residency Showcase**: 3/25/2017 @ 11:30 AM—1:00 PM PST
- **Rutgers Roundtable Session (2)**: 3/26/2017 @ 9:30—10:30 AM PST
- **Rutgers Receptions**: 3/26/2017 @ 6:30—8:30 PM PST

Additionally, for our spring / summer season, we have partnered even more closely with the University Outreach Committee (UOC) to coordinate visits in the same region to occur around or on consecutive days. Combining school and organization visits has allowed us to minimize substantial increases in costs by effectively utilizing our budget. Thank you to all the fellows who partook in visits thus far. Below is an overview of the many great meetings RPIF has and will be participating in this fellowship year.

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<thead>
<tr>
<th>Event</th>
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<tr>
<td>TSHP 2017</td>
<td>Galveston, TX</td>
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<td>SNPhA Regions III, IV, and V 2017 Conference</td>
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<td>SNPhA Regions I &amp; II 2017 Conference</td>
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<td>APhA Region 6</td>
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<td>APhA Region 7</td>
<td>Salt Lake City, UT</td>
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<td>Illinois Council of Health System Pharmacists</td>
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<td>American College of Clinical Pharmacy (ACCP)</td>
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<td>Academy of Managed Care Pharmacy (AMCP) Nexus Educational Conference</td>
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<td>Pharmacy Society of Wisconsin 2016 Annual Meeting</td>
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<td>Rutgers EMSOP Career Fair</td>
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PDD FEEDBACK COMMITTEE UPDATE
By: Ramya Mathew, Pharm.D., and Prity Avichal, Pharm.D.

The year of 2016 was a great year for the PDD Feedback Committee. We accomplished many things, with the greatest accomplishment being able to present our research poster on behalf of the RPIF program at DIA Annual 2016 in Philadelphia, PA. The poster, ‘Use of a Mobile Robot to Facilitate Long Distance Professional Development Meetings For Post-Doctoral Fellows’, was in conjunction with the Technology Committee, Patrick Liu and Rubin Modi, and Dean Barone and Dr. Toscani. The poster was a great success, and we were even able to bring our fellowship robot RUD2 along with us to display.

We also had to say goodbye to our beloved PDD Feedback co-chair, Priya Ramachandran, who completed her two-year fellowship and began full time at her partner company, Novartis. In July, we welcomed almost 100 new Fellows, as well as Prity Avichal, who is our new PDD Feedback co-chair. Prity is a two-year Regulatory Affairs Fellow at Johnson & Johnson. She has brought great, innovative ideas on ways to improve and streamline our PDD Feedback process, which we will be implementing in the coming months.

ARE U.S. SCHOOLS OF PHARMACY MEETING STUDENTS’ GROWING INTEREST IN INDUSTRY?
By: Stephani Strasburger, Pharm.D., M.S.

Two current pharmacy students, one at Oregon State University, and another at MCPHS, explored this question through an extensive research project spanning approximately one year, and culminating in a poster presentation at the ASHP Midyear Clinical Meeting on December 6, 2016. The project analyzed industry-related courses offered by colleges of pharmacy throughout the United States by reviewing student handbooks, course catalogs, and course syllabi.

Importantly, the results confirmed that the prevalence of industry-relevant courses is significantly higher in regions with the highest geographical industry concentration. The highest percentage (52%) of pharmacy schools offering industry-relevant courses is located along the east coast, while the lowest percentage (14%) is located in the Pacific Northwest. Overall, 41% of colleges of pharmacy offered one or more industry relevant courses, with the most common (26%) topic being Health Economics and Outcomes Research (HEOR).

Another important finding is that only 13% of the electives identified and reported upon in this research incorporate various aspects of pharmaceutical commercialization from drug development and regulatory approval to marketing and sales. As a result, relatively few student pharmacists are able to develop an understanding of various departmental functions or the key roles that industry pharmacists play within the pharmaceutical industry. This knowledge is essential for students who apply for post-graduate industry fellowship programs and direct entry-level industry positions, as the competition for securing these positions continues to increase.
The RPIF Newsletter would like to welcome Dr. Hermes-DeSantis to this edition of our Faculty Spotlight section! Dr. Hermes-DeSantis is a great resource for both pharmacy students and Fellows that might be seeking the utmost highest source of expertise on drug information. She is currently the Director of Drug Information Services at the Robert Wood Johnson University Hospital, and is concurrently a Clinical Professor at the Ernest Mario School of Pharmacy. We don’t know how she does it! We recently sat down with her for a Q&A of what it’s like to be in her shoes for a day.

What drew you to the field of pharmacy?

In high school, I remember precipitating silver powder in chemistry class, which I thought was very cool. I decided I wanted to combine that with my desire to help people and thought of biochemistry, which lead me to pharmacy.

Tell us how you first got involved with the RPIF fellowship program?

My first interaction with the Fellows was as a Doctor of Pharmacy student, we had rotations with some of the Fellows and they attend our seminar presentations.

What advice do you give Fellows that want to stay involved with the field of pharmacy outside of their industry role?

Getting involved with professional organizations that are beyond just the industry perspective as well as with their alma mater’s Alumni Association to impact the next generation of pharmacists.

Where do you see the future of the profession headed?

Pharmacy has some many different ways that it can go, and will probably go in all of them. The interprofessional aspect of the pharmacists role can’t be understated. Providership status is one of the next hurdles for the profession to cross, but it isn’t the only one. As the profession continues to shift and morph, issues will continue to present themselves and pharmacists, in all aspects of the profession, will continue to address them.

What are some of your other interest, outside of pharmacy?

Outside of pharmacy, my husband and I have a wonderful therapy dog that he volunteers with at local hospitals, we also enjoy time in the mountains fishing, traveling, and spending time with family and friends. We are also avid historians and actively participate in living history events.
ALUMNI CLASS NOTES
Where are they now?

Bryan O’Sullivan ’13 – Bryan recently started a job as a Medical Science Liaison (MSL) with Boehringer Ingelheim. This move follows nearly four years of post-fellowship home office medical affairs experience at AstraZeneca and Novo Nordisk, including roles in publications, medical strategy, and stakeholder engagement. As an MSL, he will support the field medical team, seeking insight to inform clinical and medical strategy and building relationships with key scientific experts in the Philadelphia area. Bryan completed his fellowship at Bristol-Myers Squibb.

Viraj Degaonkar ’16 – Viraj completed a Clinical Development Fellowship at Novartis in 2016. Shortly after, he relocated to San Francisco after accepting a position with Genentech as a Clinical Science Associate. Viraj now supports the late stage clinical trial development for the use of cancer immunotherapy in the treatment of bladder cancer.

Julia Hautmann ’16 – Julia is currently living in Denver, CO, and working as a Teva Respiratory Medical Science Liaison covering the Rocky Mountain territory (CO, UT, NM, AZ, NV). Colorado is incredible, and her husband, two pups, and her all enjoy exploring the mountain trails. She travels a lot for work, which she loves, but is very excited to settle into our new home which they recently bought.

Erica Hosek Dankiewicz ’12 is enjoying life as a new mom since giving birth to her daughter Annika this past October. While it can still change, Erica is hoping her daughters hair color stays its strawberry blond hue so the two of them can be ginger twins! While she has recently returned back to work at Acorda Therapeutics, Erica started her industry career as a Medical Information/Medical Affairs Fellow at Bayer Healthcare. Congratulations Erica & family!
US-Cuba relations could be big for pharmaceuticals

Cuba has gained international attention for its biotech and pharmaceutical industry, particularly for the development of a potential vaccine for one type of lung cancer. Historically, Fidel Castro was in favor of funding innovation but due to the political climate, that innovation has gone untapped until now. The potential vaccine for one type of lung cancer has entered into a research trial, which has opened up opportunities for 20 other cancer treatment options that have been developed in Cuba. No matter the outcome of the trial, it is vital that Cuba be recognized for its potential to contribute to emerging therapies. Overall, it is important to be aware of Cuba as an untapped and evolving source of innovation.

FDA grants removal of the Black Boxed Warning on Pfizer’s varenicline

An independent panel to the FDA voted in September to remove the black boxed warning on Pfizer’s varenicline, a smoking cessation agent. The warning was introduced in 2009 after thousands of reports of agitation, hostility, and suicidal thoughts. Pfizer presented results from the EAGLES study, in which they compared varenicline and Zyban against placebo or a nicotine patch to show that there was no clear evidence of causality to those serious side effects. The decision prompts many questions from critics, including the standards to present data and review process for removals of black boxed warnings.

Quincy Bioscience LLC hit with lawsuit targeting Prevagen® memory claims

The Federal Trade Commission (FTC) and the New York State Attorney General filed a lawsuit against Quincy Bioscience LLC, the makers of the dietary supplement, Prevagen®. The lawsuit is due to the lack of evidence in supporting the product’s claims of improved memory impairment made in a multi-channel advertising campaign that targeted vulnerable, elderly consumers. The FTC is seeking refunds for all consumers who have purchased the product since its profitable launch in 2007.

Flu Season in FLU-swing!

Flu season is in full swing! The CDC reports this year’s flu is “worse than last year”. The hardest hit states are New York, New Jersey, Oregon, Washington, and Oklahoma. The good news is there is still time to get vaccinated! Early reports indicate this year’s strain of flu closely matches those covered by the flu vaccine.
CLINICAL UPDATE CORNER
Hot Topics Impacting Healthcare and the Pharmaceutical Industry

FDA Approves First Spinal Muscular Atrophy Drug: Spinraza™

The FDA approved Spinraza™ in December 2016. Spinraza™, developed by Biogen, is the first approved treatment for Spinal Muscular Atrophy (SMA) in pediatric and adult patients. SMA is characterized by a loss of motor neurons in the spinal cord and lower brain stem that can lead to severe and progressive muscular atrophy and eventually paralysis. Spinraza™ was approved based on multiple clinical studies, the largest of which was the ENDEAR Trial. ENDEAR showed that patients on Spinraza™ had sustained clinically meaningful improvement in motor function and lower mortality compared to placebo.

By: Daina Nanachanatt, Pharm.D.

Positive Topline Results from the First Phase III Studies of an Investigational Two Drug HIV Regimen

Since the adoption of HAART in 1996, treatment of HIV has generally required three to four antiretroviral agents. In December 2016, it was announced the first phase III studies (SWORD 1 & 2) of an investigational two drug HIV regimen (dolutegravir + rilpivirine), being developed through a collaboration by ViiV Healthcare and Janssen Pharmaceuticals, had met their primary endpoint. These studies showed that in virologically suppressed patients on a three or four drug regimen, switching to dolutegravir + rilpivirine was found to be non-inferior at 48 weeks to remaining on the original regimen, in terms of maintaining viral suppression (proportion of patients with HIV-1 RNA <50 copies/mL). If approved by the FDA, this two drug regimen is expected to represent a paradigm shift in the way that HIV is treated.

By: Paul DiPietro, Pharm.D., MBA

Jardiance approved by FDA for reduction in CV death in adults with Type 2 Diabetes

On December 2nd, the FDA approved Jardiance (empagliflozin) as the first product to reduce cardiovascular death in adults with type 2 diabetes and established cardiovascular disease. The data submitted to the FDA for approval of the new Indication stemmed from the EMPA-REG trial which was first shown at the 51st Annual Meeting of the European Association for the Study of Diabetes (EASD) 2015 and was subsequently published in the New England Journal of Medicine. The study was able to show a 38% risk reduction in CV death for patients on empagliflozin as opposed to those solely on standard of care. Looking forward, it will be interesting to see how clinical practice in T2DM changes with the recent influx of cardiovascular outcomes data.

By: Dhaval Patel, Pharm.D.

Amgen Wins Sales ban on Sanofi’s Praluent

U.S. District Judge, Sue Robinson, ordered Sanofi and Regeneron to halt Praluent sales for 12 years due to patent infringement on Amgen’s Repatha. The ban is to take effect 30 days from the court ruling, allowing time for Sanofi to appeal the sales ban. Banning Praluent would harm patients who take lower doses of the PCSK9 cholesterol–fighting drug than what is available with Repatha. Praluent was expected to generate $2 billion in sales by 2020.

By: Vivian Nguyen, Pharm.D.
The Fellowship Chronicles | March 2017

CLINICAL UPDATE CORNER
Hot Topics Impacting Healthcare and the Pharmaceutical Industry

21 Century Cures Act Signed Into Law

A major healthcare bill was signed into law by President Obama on 13-Dec-2016 following strong bipartisan support from the Senate (94-5) and the House (392-26). The bill authorizes up to $6.3 billion of federal support for various endeavors, including high-risk, high-reward initiatives (Cancer MoonShot, BRAIN, Precision Medicine) and drug abuse prevention/treatment programs. It also allocated funding for the FDA to support breakthrough medical technologies and big data management.

Link for more information:

The 45th takes on Drug Pricing

Drug pricing is always a hot-button issue, and with Donald Trump taking over as POTUS, its buzz has not diminished. In a press conference prior to his inauguration, Trump told Time magazine that he was “going to bring down drug prices” given his dislike for the current pricing situation. How President Trump planned on dropping drug prices, however, remained unclear. The new Commander-in-chief swayed a number of times on his drug pricing policies during his campaign, wavering in his support for drug reimportation and Medicare pricing negotiation. So, until Trump delivers concrete plans to lower prices, it is safe to say the drug pricing debate will remain at the forefront of political headlines. The public will continue to call for the industry to cut prices, and big Pharma will continue to remind them that decreased prices will sacrifice innovation and potential patient cures.

Link for more information:

TECHNOLOGY COMMITTEE UPDATE
By: Rubin Modi, Pharm.D., Daniel Seniuk, Pharm.D., and Daniel Shu, Pharm.D.

Each year the technology committee takes on the huge task of scheduling interviews for hundreds of candidates at the ASHP Midyear conference which is a vital component of recruitment process for the RPIF program. The number of candidate interested in applying to the program grows each year and so do the challenges of scheduling. The 51st ASHP Midyear conference was no different and the technology committee was put to the challenge of scheduling a record breaking 635 candidates. With effective strategy from the committee chairs, upgrade to wireless technology, and support from other Fellows, the interview scheduling process was completed in less than 4 hours. The technology committee is determined to repeat the success at the 52nd ASHP Midyear conference in Orlando later this year.
WHERE IS THE GRASS GREENER?
By: Brian Ung, Pharm.D.

Unlike many other Fellows, I did not have an APPE rotation at a pharmaceutical company. My introduction to the pharmaceutical industry and health economics & outcomes research (HEOR) came at a consultancy, Xcenda. At Xcenda, I was exposed to and involved in several project types that are part of at my current role at Celgene including; value proposition development, payer research, dossier updates, and everyone’s favorite, literature searches. During my rotation I also learned about the dynamics of the consultant-client relationship and the communication needed in order to work together. My first project at Xcenda involved identifying areas of unmet need and disease burden for the client’s product and illustrating how Xcenda’s services could aid with the drug launch. Now being at Celgene, it’s been fascinating being on the receiving side of the request for proposals. I’ve noticed a few differences between the two work settings. At a consultancy, you touch many more disease states, but do so at a much higher level, rather than the deep dive that is required at a pharmaceutical company. At Celgene, I feel like my role involves more study design, development and project management rather than the hands-on work I was a part of at Xcenda. Not sure which side I like better, but I will say Celgene has the better coffee machine.

HOW TO COLLABORATE WITH THE MLR TEAM
By: Caroline Kim, Pharm.D.

MLR, PRC, CAT are all commonly used acronyms to describe the Medical, Legal, and Regulatory Review (MLR) team; the gatekeepers of pharmaceutical product promotions. The MLR team reviews all technical, educational, and promotional materials in a cross functional team to provide strategic support while ensuring the information is accurate and complies with FDA regulations, company policies, applicable laws, and other issues that might create liability risk for the company.

Whether you sit on the MLR team as a regulatory or medical reviewer, or are developing disease-state information or marketing strategies for MLR review, you will have opportunities to interact with the entire team cross-functionally. I had a chance to speak with marketing, commercial, and medical members of the MLR team and have included some tips you can implement for an efficient review process:

- **Get the MLR team involved early.** This will give Project Owners an opportunity to get directional guidance and avoid spending a lot of effort on a project only to find out the core of the piece has to be changed. Share ideas with the MLR team and show them the big picture early on. You would be surprised- MLR team can be creative too. For Reviewers, keep in mind that the Project Owner needs clear and complete guidance to develop the material that you would be ultimately reviewing.

- **Communicate effectively.** For Project Owners, be clear of the messages you are trying to communicate and eliminate confusion. For Reviewers, be clear to communicate why something cannot be approved to avoid reoccurrence in the future. **No one likes surprises- unless they are chocolate.**

- **Pick your Battles.** Be prepared to defend your work, but save your energy for the most important messages. Identify what is business critical and what is nice-to-have.

- **Treat everyone with Respect.** Differences in opinion are inevitable, but learn to understand each other’s vision and treat everyone with respect. It may be challenging to reach an agreement during MLR review, but just remember we are all working toward the same goal. A senior director on global and brand marketing at Acorda Therapeutics summarized it best when he said the underlying drive to his work is to “Do Right by the Patient.”
UPCOMING DATES

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<tr>
<td>March 12</td>
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<td>May 29</td>
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<td>Certificate Dinner for Graduating Fellows</td>
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FIND THE FISH

Found the hidden emoji in this issue? If so, be the first to email the Newsletter Committee with an attached screenshot of the fish for a special reward!

Congratulations to our December winner: Zac Post!

CONTACT THE NEWSLETTER COMMITTEE

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Please contact us if you are interested in writing for the next edition of the Fellowship Chronicles. Special thanks to all of our contributors!

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