



# The Fellowship Chronicles

Official Newsletter of the Rutgers Institute for Pharmaceutical Industry Fellowships



## Congratulations to the Class of 2017, and our Class of 2017 Teaching Certificate Recipients!

### In this edition:

- Faculty Spotlight welcomes a former fellow, Dr. Volino!
- Exploring the origin of drug brand names
- Genentech gives back
- Updates from PDD, UOC Committees
- Insight into Sports nutrition supplements



2016-2017 Newsletter Committee Co-Chairs final farewell tour. Thank you all for a great season! And as always, keep reading!  
*#joestine*

**C**ongratulations to all the graduates of this year's fellowship class of 2017! We celebrated their achievements at this year's annual certificate dinner located at the Westin Princeton Hotel on Thursday June 1, 2017. This year we graduated **65 fellows** from **15 different companies!** As the year winds down, a new year is about to commence and we look forward to welcoming the new incoming fellows during orientation on Friday June 30, 2017.

Our Teaching and Learning Certificate graduates of 2017 recently celebrated their accomplishments! Congratulations to all **24 graduates** of this year's Teaching and Learning Certificate program!



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# WHERE DO BRAND NAMES COME FROM?

By: Peter Chan, Pharm.D.



This year has come with newly approved drug names such as Dupixent, Kisqali, and Xadago. Where do these strange names come from?

Over the past few months, I had the privilege of working on a **trademark development project**, which revealed just how complex the process of creating the perfect brand name can be. It all begins with deciding on qualities the new brand name must embody. Hundreds and hundreds of potential names are generated for review, then begins the game of winnowing out the bad ones. Sequential processes, including screening meetings (where a global team sits and eliminates names one by one), legal analysis, market research, and regulatory testing around the world- where even more names are eliminated. After about two years of review, hundreds of names become just one- a powerful global trademark that will hopefully add to the success of the product.



As pharmacists, we have practical experience and unique skills that help us contribute to the drug naming process. Few professions rival our lexicon of both brand and generic names- strange as they may be.



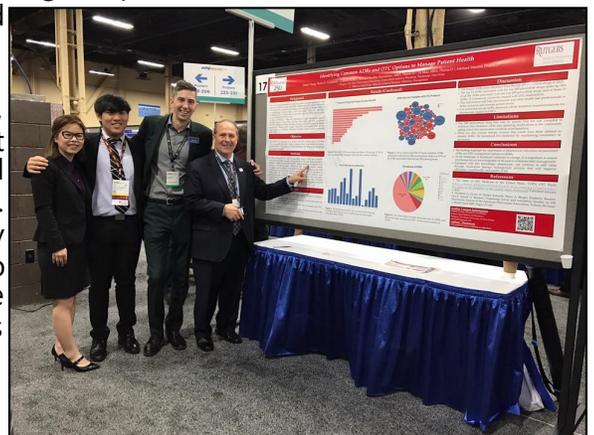
## The Hottest Collaboration in the Industry:

*Ernest Mario School of Pharmacy (EMSOP) x Rutgers Pharmaceutical Industry Fellowship (RPIF)*

By: Daniel Chang, Pharm.D. Candidate Class of 2019  
Ernest Mario School of Pharmacy

As a 4<sup>th</sup> year pharmacy student at Rutgers University, I had the opportunity to collaborate with two Johnson & Johnson Consumer fellows, **Richard Bradley Rzendzian** and **Yu Mao**. Under their mentorships, I gained tangible experiences by **co-lecturing** a class on drug development, creating and presenting a poster at ASHP Midyear 2016 highlighting the potential of over-the-counter (OTC) medications to improve patient quality of life (QOL), and **networking** with other Rutgers fellows.

Through these opportunities, I improved my professional skills, which are not taught didactically. Although Dr. T's advice that academics come first as a student resonates, I see the additional value in exploring pharmacy **outside the classroom setting**. Shadowing fellows in the industry setting has supplemented my classroom learning immensely: it has shown me what I want to achieve as a pharmacist. Therefore, I will continue to collaborate with the RPIF community and am grateful for the experiences that I have had thus far.



(L-R): Yu Mao, Daniel Chang, Brad Rzendzian, and Dr. Toscani



## U.O.C. YA IN THE FALL!

*University Outreach Committee Updates*

By: Brielle Carramusa, Pharm.D., and Alex Oladele, Pharm.D.



The goal and purpose of the University Outreach Committee (UOC) is to provide exposure to pharmacy students about potential career opportunities within the pharmaceutical industry, and within the RPIF Program, through outreach visits. Fellows visit pharmacy schools and provide either a presentation with a Q&A session, or an informational booth at a showcase on campus. RPIF Fellows have also been invited to participate in panels, roundtables, and other networking events put together by student chapters of pharmaceutical organizations like Drug Information Association (DIA) and Industry Pharmacists Organization (IPhO). Through these visits, students get an overview of key areas within the pharmaceutical industry through practical insights and experience from our fellows. This fall, RPIF visited **60 pharmacy schools** in preparation for recruitment season. We were welcomed back at schools all across the country, from University of Illinois at Chicago to Nova Southeastern University in Fort Lauderdale, FL to University of California -San Francisco. We also partnered with **15 new schools**, including University of Missouri-Kansas City and West New England University. The program reached record high of 2,158 students in the fall, a **58% increase from last year**.



The UOC co-chairs visit Chicago, IL

We have just concluded the Spring 2017 UOC season, with 29 visits completed and an expected **450+ students reached**. The University Outreach Committee will continue to expand the RPIF reach by partnering with new schools, fostering existing relationships, and providing an increasing number of students with insights and opportunities. Preparations will begin over the summer, and then it's full speed ahead for the Fall 2017 UOC season! Stay tuned!



Fellows visiting several campuses and states across the nation! Including but not limited to: Georgia, Massachusetts, Kentucky, Missouri, etc!



## SPORTS NUTRITIONAL SUPPLEMENTS:

*Are they FDA approved?*

By: Avni Shah, Pharm.D. Candidate Class of 2021

*Ernest Mario School of Pharmacy*

In the same way Americans phase through fashion fads, health and nutrition has played cyclic roles in the lives of the average American. With the rise of technology in daily life, fitness is coming to center stage. Social media provides a wide-reaching platform for professional body builders to influence Millennials to develop personal goals in and out of the gym. However, to the unawareness of consumers, the marketing of sports nutritional supplements **lack a stamp of approval** by the Food and Drug Administration. Consumers may visually see the outstanding results of such supplements on fitness influencers; yet, the absence of approval by the FDA puts the safety of the supplements in question.



## COMPANY SPOTLIGHT:

*New Pharmacy Organization Created at Celgene*  
By: Brian Ung, Pharm.D.



Through the collaborative efforts of current employees and post-doctoral pharmacy fellows, a new pharmacy organization has formed at Celgene: the **Celgene Pharmacists Network (CPN)**. Focused on promoting the professional development of pharmacists within the company, the CPN strives to create an internal network for members to connect cross-functionally. Furthermore, through events such as continuing education (CE) sessions, community outreach, and engagement with external societies, the ambition is to establish Celgene as a leader/supporter of the pharmacy profession.

On Tuesday, April 11<sup>th</sup>, the CPN hosted their **kick-off meeting in Summit, NJ**. The kick-off meeting consisted of an introduction of the core team, composed of employees and post-doctoral fellows, an overview of the CPN, and a CE session **"Highlights of 1000+ Medication Reviews During Transition of Care"**, presented by **Dr. Linda Gooen** of the New Jersey Pharmacists Association.

What was the motivation for creating a pharmacy organization at Celgene?

"Realizing that Celgene did not have a pharmacy organization served as the motivation for working on this initiative. As a group, we saw the added benefit for both the employees and Celgene of creating a **network for pharmacists** to interact with one another cross-functionally while providing a means to promote individual professional development. Through this pharmacy organization, referred to as the Celgene Pharmacists Network, we envision the organization to become a **beacon** for pharmacists across the company to be a part of in order to facilitate communication among members, serve as an internal resource, and promote Celgene as a leader in the pharmacy field."

- *Joseph Pariseau (Former RPIF Fellow, Associate Clinical Research Scientist)*

"The motivation came during a conversation between the current Celgene pharmacy fellows and Lisa Drucker, a pharmacist and Celgene employee in Regulatory Affairs. We realized there are probably more pharmacists working at Celgene than we knew, across various functional areas and we wanted to find a way to bring us all together. We knew other Pharma companies had organizations devoted to Pharmacists, and wanted to create something similar here at Celgene. Initially we wanted to begin by providing CEs and social events to connect us all together, and from there the **idea of CPN formed.**"

- *Emily Mantovani (Clinical Research & Development Fellow, Associate Clinical Research Scientist)*



(L-R): Kevin Sharkey, Kripa Sanghavi, Monica Azer, Emily Mantovani, Peter Fendt, Linda Gooen, Brian Ung, Joseph Pariseau, Stephen Lee

### Do companies benefit from having employee organizations such as CPN?

"Absolutely. While role of the industry-based pharmacist is well established, an employee network or organization such as CPN formally **connects the pharmacist community** to provide opportunity for things such as **learning, development, mentoring and best practice sharing** among like-minded individuals thus continually enhancing the value delivered by the pharmacist throughout the organization."

- *John Berg (Vice President, Corporate Medical Affairs)*

"The CPN seeks to facilitate **cross-departmental networking** and strengthen relationships between pharmacists throughout Celgene. In turn outreach events being planned will allow us to expose external talent to the value of the CPN, and the broader value of being a part of the Celgene family."

- *Peter Fendt (Global Market Insights Fellow)*

### What were some of the internal or external partners you worked with to establish the organization and kick-off meeting?

"Establishing the organization also required **partnerships** across several internal functional areas which was generated through the CPN "Core Team". Additionally, we leveraged relationships with HR and IT to help us create the network and CPN site on the Celgene intranet."

- *Kripa Sanghavi (Regulatory Affairs Fellow)*

"Celgene has a large contingent of field-based pharmacists. CPN is an inclusive organization offering its benefits across all departments, **both New Jersey-based and beyond**. There was resounding response by those pharmacists throughout the US with the desire to be part of such an important network."

- *Rob Jankowski (Director, Hematology MSLS)*

### How do you think CPN can further grow?

"We are still in the early stages of development, so there are many opportunities to shape the trajectory of this new organization. There is a significant pharmacist community here at Celgene that encompasses many different functional areas, so it will be excellent to tap into that **diversity** and raise awareness of the unique skill set that pharmacists have to offer. I think a key area of growth continues to be creating **professional development opportunities** for pharmacist colleagues through various outlets, such as speaker series, networking events, and continuing education, in order to increase visibility of the CPN. This is certainly an exciting time for the CPN!"

- *Krista DeLissio Hudak (Senior Clinical Research Scientist)*

"The Celgene Pharmacist's Network (CPN) has provided me with the opportunity to pay it forward in reaching out to pharmacy students across the nation. This month the CPN, in conjunction with IPhO, and Celgene US Medical Affairs are **hosting 10 pharmacy students** across the nation to learn more about the pharmaceutical industry and network with Celgene pharmacists. This network, although new, has set precedence for cross-functional collaboration, networking, and outreach within the pharmacy community."

- *Monica Azer (US Medical Affairs Fellow)*





## GENENTECH GIVES BACK:

*A Continuing Education and Networking Event*

By: Brandon Croft, Pharm.D.

The third annual Continuing Education event at Roche/Genentech in South San Francisco was recently held in April to provide pharmacists and other interested employees an opportunity to network and learn more about current trends within industry.

The ***Evolving Trends in Patient Care and Access***: A Continuing Education and Networking Event was hosted by current post-doctoral fellows across the organization, primarily within Rutgers Pharmaceutical Industry Fellowship Program, and was comprised of three 1-hour informational sessions and a networking lunch.

Session topics included:

- Speed to Innovation: Orphan Drug Designation and Rare Disease Drug Development
- Real World Evidence: Understanding the Value of Data Generation
- Pathways vs. Guidelines: Impact on Clinical Decision Making

Over **150 pharmacists** and interested employees across a broad spectrum of industry disciplines attended the event this year, receiving up to 3 contact hour credits.



**Anna Gruzman**  
Regulatory



**Tian Sun**  
Regulatory



**Vivian Nguyen**  
Medical Affairs



**Brandon Croft**  
Clinical Science



**Alexandra Markus**  
Clinical Operations

## HOW TO SEE AN OPPORTUNITY IN A DIFFICULTY

By: Monisha Prakash, Pharm.D. Candidate Class of 2017  
*University of the Sciences Philadelphia College of Pharmacy*



**B**eing an international student I have faced more employment restrictions than I could have ever imagined. Here are some quick tips you can implement during pharmacy school to set yourself up for success despite restrictions.

**Use your resources**- When in pharmacy school, we are provided with an immense connection of pharmacists. If someone can't directly help you, they could direct you to at least one person for assistance. After speaking to many people, one professor connected me to a pharmacist who allowed me to volunteer at his pharmacy for licensing hours.

**Get involved on campus** – Professional pharmacy organizations provide students with a platform to learn about different sectors of pharmacy, career opportunities, and participate in community service projects. Taking on leadership roles can help learn transferrable skills that one may learn on a job.

**Do research** – Rotations is a great time to get certified in the Collaborative Institutional Training Initiative program and obtain clinical research experience that may change patient care. To get industry exposure, I also did an independent study to learn the role of payers.

**Pick up a minor**- It is always useful to have a breadth of knowledge. Starting freshman year I picked up a Pharmaceutical Healthcare Business minor that enhanced my learning curve on rotations. Don't be afraid to **ask for help**, everyone has their own story and can help you in their own way.

## FACULTY SPOTLIGHT

Featuring: Dr. Lucio Volino, Pharm.D.

In this edition of the RPIF Newsletter, we would like to introduce Dr. Lucio Volino as this month's faculty spotlight! Dr. Volino is currently a Clinical Associate Professor in the Pharmacy Practice and Administration Department at The Ernest Mario School of Pharmacy, Rutgers, The State University of New Jersey. After receiving his Doctor of Pharmacy degree from Albany College of Pharmacy, Dr. Volino completed a **post-doctoral fellowship** in clinical research and regulatory affairs at **Novartis Pharmaceuticals Corporation**, in conjunction with The Ernest Mario School of Pharmacy Pharmaceutical Industry Fellowship Program. At the school, he is involved with a plethora of activities and we had the pleasure of sitting down with him for a Q&A of what it's like to be in his shoes as a former fellow and now a professor!



What drew you to the field of pharmacy?

The variety of opportunities available to pharmacists. When I finished my undergraduate program, I was interested in so many different areas (research, science, helping others, and teaching). **Pharmacy brought all of those pieces** together with the ability to practice in an array of settings.

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

With the support of my amazing BMS and Novartis preceptors/senior fellows, I was fortunate enough to attend **two PDD's**, while on rotations. When I graduated pharmacy school, I joined the fellowship program (Medical Affairs/Regulatory Affairs) with Novartis Pharmaceuticals.

What advice do you give Fellows?

**Enjoy the moments.** Your time in the fellowship program flies by quickly, so make the most of it. Experience as much as you can and get to know other fellows, especially those from other companies.

What are you involved with at the Pharmacy school? And are there any ways for current fellows to contribute?

I am involved in a variety of committees, courses, and student organizations at the school. There are many ways to contribute as a fellow. You can teach, do research with students/faculty, participate in or speak at a student organization function, mentor students, etc. **The list is endless.** As a fellow, I was fortunate enough to teach in the Pharmacy Communications courses, which I now coordinate with two other faculty members. My experiences helped solidify my passion for teaching. If you have a passion or an interest in something, reach out to someone at the school or in the fellowship program. There is a high probability that someone at the school is doing it or can work with you to develop the idea.



**Gus Volino**

Favorite Activities:  
chasing birds,  
food

What are some of your other interests outside of pharmacy?

Right now, **Gus, our 8-month old German Shorthaired Pointer puppy**, is the focal point of my activities outside of pharmacy. His love of food and pointing at/chasing birds keeps both of us busy. When he is not doing one of those things, I get to enjoy cooking and refining my adult beverage **mixology skills**. Cheers!

## ALUMNI CLASS NOTES

### Where are they now?



**Brett Hensley '14** – Brett joined Sanofi US after completing his fellowship at J&J and worked almost 3 years within Medical Information. Earlier this year, Brett returned to J&J as a Medical Information Manager on the Solid Tumor Oncology team. He is very excited to support a new therapeutic area with such a dynamic and diverse pipeline. Along with this exciting career move, Brett and his wife Sarah had a baby girl, Alice, in September 2016. She's quite the goofball, just like her old man!

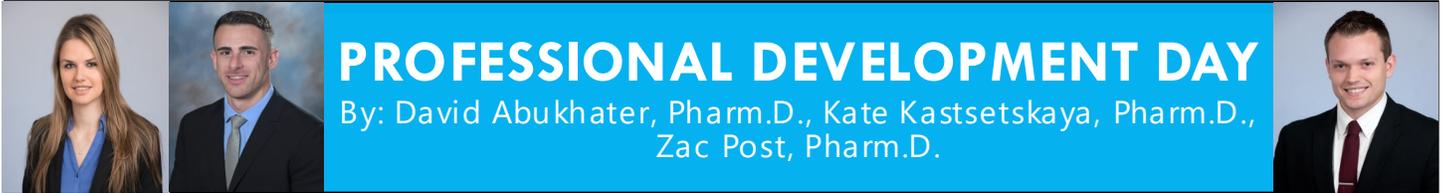


**Adrienne Aiello '12** – Adrienne joined Sanofi Genzyme in 2012 as Principal, Scientific Publications, and was responsible for developing and implementing the publication plan for Cerezyme and supporting Medical Communications for the Gaucher portfolio. In 2015, she took on the role of Manager, Scientific Publications & Communications, and since has led the implementation of publication plans and Medical Communications strategy for the global Rare Neurology portfolio, including alglucosidase alfa and neoGAA. In addition to her responsibilities as Publication and Medical Communication lead for Pompe, in the past year, Adrienne co-directed the Pharm D. Fellowship program for Sanofi Genzyme overseeing the strategy for rotations and educational opportunities for 20 fellows. Importantly, Adrienne played a leadership role in mentoring and training fellows across Rare Disease medical communications projects and is invested in developing and retaining new talent within Sanofi Genzyme MA teams.

**Jerald Grace '12** – Jerald recently received a promotion to Program Director of Product Development Regulatory Affairs at Genentech. This promotion is a result of Jerald's strong leadership and strategic contributions to multiple high-profile immuno-oncology and broader oncology programs since he joined Genentech in 2014. Jerald has been a part of the Roche-Genentech family since completing his Regulatory Affairs fellowship with Roche in 2012. Congratulations Jerald!



**Eddy Arthur '17**—Eddy completed his 2-year clinical research fellowship training at Pfizer Inc. in the Consumer Healthcare division. After what he calls a truly rewarding and well-rounded experience in clinical research and study design, he joined the group permanently as Senior Manager in Global Clinical Research. He supports the organization's efforts in bringing innovative solutions to millions of consumers worldwide. In addition, as a testament to the tremendous opportunities afforded to Pharm.Ds in the Rutgers Fellowship program, he is well on track in completing his Masters in Business Administration at the Rutgers Business School with a concentration in Pharmaceutical Management.



## PROFESSIONAL DEVELOPMENT DAY

By: David Abukhater, Pharm.D., Kate Kastsetskaya, Pharm.D.,  
Zac Post, Pharm.D.

The Professional Development Day (PDD) Series was created to enhance presentation skills, promote connectivity and a sense of community across different companies and disciplines, develop new skill-sets under the guidance of external trainers, and inform the fellowship community of current issues facing the pharmaceutical industries. In effort to build upon these already impressive objectives, the PDD committee worked tirelessly to implement new programs that drive additional value through transferable skill development and enhancement of relationships within our internal and external network. The **Corporate Advancement Series (CAS)** and transferable skill workshops have been a major success during the 2016-2017 fellowship class and touched upon dining etiquette, social styles, innovation, facilitation and moderation, leadership, and effective communication in various settings. Additionally, due to the successful execution of *Leadership Spotlight* installments and "Meet the Preceptor" segments, fellows received invaluable career advice from the likes of **Gerald Finken, MS, RPh; Bruce Kimelblatt, BS, PharmD, MBA, RPh; Megan Zoschg Canniere, PharmD; Bruce Epstein, MBA, RPh; and attending preceptors** within the fellowship program.

For the 2017-2018 fellowship class, the PDD committee will continue to innovate and deliver engaging workshops. Fellows can anticipate curated workshops that target personal branding, networking, interview preparation, financial management, and much more with the commencement of PDD in July. Additionally, after a very successful pilot in the Spring of 2017, Line Function Discussions (LFDs) will continue to be incorporated into the PDD Series on a regular basis. The concept of LFDs was introduced to encourage and facilitate inter-company discussions among fellows to align their fellowship experiences. The PDD Committee is looking forward to continuing to enhance the RPIF Program in 2017 and 2018 with these innovative workshops and initiatives.



## THE FINE LINE BETWEEN BREAKTHROUGHS AND BURNOUTS

By: Rohan Chittella, Pharm.D. Candidate Class of 2019  
*Ernest Mario School of Pharmacy*

The day to day grind of being a Rutgers Fellow, although rewarding, is nothing short of demanding. From preparing for their daily activities at their respective companies to attending and participating in professional development days (PDD), Fellows are consistently pushed to their max. As a result, they tread the fine line between breakthroughs and burnout. I recently caught up with **Carmelo Alonso, Pharm.D**, a Cardiovascular Medical Strategy/Medical Science Liaison at Bristol Myers Squibb to find out how he **balances the stresses of life and work**, while maintaining health.

"For me, it has always been important to incorporate exercise in my life. I know that when I'm really stressed, I can use exercise to sweat out my frustrations. Playing basketball is one of the things I do to prevent getting overworked in the first place. Basketball is a great way to connect with friends and challenge yourself physically. After playing, I find myself **reenergized** and ready to tackle whatever I have on my plate."



Fellows and Rutgers pharmacy students engage in a healthy basketball pick up game post PDD

## CLINICAL UPDATE CORNER

*Hot Topics Impacting Healthcare and the Pharmaceutical Industry*



By: Vineeth Nair

### **FDA Approves Harvoni & Sovaldi for Pediatrics**

In the United States, almost 46,000 children and adolescents have Hepatitis C virus (HCV) infection, often acquiring it through birth. Interferon injections and ribavirin regimens are the standard pediatric treatments. However, on April 7<sup>th</sup>, 2017, the FDA approved Harvoni (ledipasvir/sofosbuvir) and Sovaldi (sofosbuvir) for use in pediatric and adolescent patients with HCV infection. These two drugs are the first direct-acting anti-viral treatments available to this population with HCV infection in the U.S. which addresses a significant and unmet public health need.

Link for more information:



By: Cindi Sounthonevat

### **No filter: A characterization of pharmacists posts on Instagram**

A new study published in the **Journal of the American Pharmacists Association** analyzed the use of the “#pharmacist” tag on Instagram. In this study, the majority of #pharmacist posts were celebratory in nature (19.7%) followed by work experience (18.6%) and advertisement (12.6%). 88% of Instagram posts containing “#pharmacist” were related to healthcare. Read the full retrospective study here:

Link for more information:



By: Sandeep Balabbigari

### **Affordable and Safe Prescription Drug Importation Act**

A new legislation titled, Affordable and Safe Prescription Drug Importation Act, is seeking to allow consumers to personally import medications from foreign countries. Currently, patients and their physicians must petition the FDA to authorize the importation of a specific medication on a case-by-case basis. While drug importation legislations have been ruled down in the past, the Affordable and Safe Prescription Drug Importation Act addresses some of its predecessors' critiques regarding drug safety. The new legislation will require foreign sellers to register with the FDA and must also meet supply chain security requirements to adhere to some of the safety standards of medications sold in the United States. The current proposal is to allow individuals to import up to a 90-day supply from Canadian pharmacies and to expand to other countries over time.

Link for more information:



By: Jennifer Moon

### **Pill Presses for Counterfeit Drug Seized in Record Numbers**

In a recent article by CNN, the US Customs and Border Protection reported seizing pill presses at a rate 19 times higher than that of 2011. This is significant because pill presses allow for counterfeit drugs to enter the American market. Counterfeit pills marketed as oxycodone or Xanax that are laced with fentanyl are becoming more prevalent and leading to countless deaths and toxicities in people. The reason why there is an increase in counterfeit drugs in the US is due to remarkably easy access to the materials needed for counterfeit drug production. In addition, the counterfeit drug industry is such a lucrative business due to the high return on investment. The article estimates that for a \$5,000-\$6,000 investment, a person could potentially make \$10 million worth of fake pills.

Link for more information:



## CLINICAL UPDATE CORNER

*Hot Topics Impacting Healthcare and the Pharmaceutical Industry*



By: Jessica Giaquinto

### **Barry Cadden Not Guilty of Murder After 64 Fungal Meningitis Deaths**

Over 13,000 people in the U.S. were exposed to fungal meningitis; leading to 700 cases and 64 deaths due to contaminated methylprednisolone injections that were manufactured and distributed by the New England Compounding Center (NECC). Results of this outbreak include change in pharmacy practices and questions of who is accountable for the loss of lives. After discovering that the NECC was attempting to pass as a drug manufacturer instead of a compounding pharmacy, congress enacted The Drug Quality and Security Act granting the FDA more authority to regulate and monitor the manufacturing of compounded drugs. The final question to answer was did the pharmacists knowingly ship out the contaminated vials with the intent to harm thousands of people? On March 22, 2017 the court answered that question by acquitting Barry Cadden, pharmacist and owner of the NECC, of 25 counts of second-degree murder.

Link for more information:



### **Industry Funding**



By: Valentina Pampulevski

A recent survey of US nonprofit organizations revealed that 8 in 10 receive support from drug, biotechnology, and medical device industries. At least 39% of patient health advocacy groups receive at least \$1 Million annually from the industry. Fifty-nine groups reported the amounts of the donations, 18 groups did not report getting funding from industry, and 13 groups did not provide any donor information. Surprisingly, only 12% of the organizations posted conflict-of-interest policies for managing potential problems. It is important to think about this information and the implications for our profession.

Link for more information:



### **FDA Extends Review Period for Baricitinib**



By: Joseph Eckart

Eli Lilly's and Incyte's baricitinib, an investigational drug for rheumatoid arthritis (RA), recently had its FDA review period extended. While its NDA was originally submitted in January 2016, the PDUFA date was extended by three months to April 2017. The extension was due to a FDA request for more information, which will constitute as a "major amendment" to the NDA. This action is of note because baricitinib poses a potentially significant development in the RA therapeutic area. It is a selective JAK1/JAK2 inhibitor; currently the only JAK inhibitor available is Xeljanz (tofacitinib, Pfizer), which is a pan-JAK inhibitor. Selective inhibition could offer a better side effect profile, and baricitinib has shown benefit compared to Humira.

### **Gene Therapy in a Patient with Sickle Cell Disease**



By: Alex Cockerham

Recent advances in gene therapy have shown promise for patients with single amino acid, homozygous missense mutation related diseases. Sickle cell disease is a genetic disease which affects nearly 90,000 patients in the United States. A child patient being treated at Reference Centre for Sickle Cell Disease of Necker Children's Hospital in Paris underwent lentiviral gene therapy in the HGB-205 clinical study. Fifteen months after treatment and continuous follow-up, the authors of the paper linked below concluded that the child had complete clinical remission with correction of hemolysis and biologic hallmarks of the disease. Moving forward, this is a small but fortunate step for the treatment of many genetic maladies for patients with only symptomatic medications for palliation.

Link for more information:



## CLINICAL UPDATE CORNER

*Hot Topics Impacting Healthcare and the Pharmaceutical Industry*



By: Edmund Arthur

### **Increasing Role of Pharmacists in the Fight Against Opioid Abuse and Overdose**

A police search in Prince's Minnesota home revealed possession of several opioid pain killers that were not prescribed to him. Law makers are taking more actions to get a better grip on the opioid abuse epidemic and prevent more lives from being lost through abuse and overdoses. Legislation in Minnesota now allows pharmacies to dispense Narcan to customers without a prescription as well as accept unused and expired medications for proper disposal. The former allows friends and family to gain access to this life saving medication conveniently whereas the latter is a move that will increase access to many residents who previously could only properly dispose unused and expired medications at police stations and specially designated collection centers. These actions highlight the increasing importance for retail pharmacists to champion patient education at the storefront in the fight against opioid abuse and overdose.



By: Maria Nduati

### **Bavencio® (Avelumab) Approved**

Merkel Cell Carcinoma (MCC) is a rare but aggressive neuroendocrine cutaneous neoplasm that is considered the deadliest of skin cancers with a mortality rate three times that of melanoma and typically occurs in sun-exposed skin in elderly or in immunosuppressed individuals. MCC has a poor prognosis in patients with advanced disease and impacts approximately 2500 Americans each year. Bavencio received Priority Review, Breakthrough Therapy, Fast Track, and Orphan Drug Designations and on March 23<sup>rd</sup> 2017 as the first and only FDA-approved anti-PD-L1 immunotherapy for adults and pediatric patients 12 year and older with metastatic MCC. The indication was approved under accelerated approval based on tumor response and duration of response. Continued approval may be contingent upon verification and description of clinical benefit in confirmatory trials.

Link for more information:



By: Parth Vashi

### **What does the future of Gene Therapy hold?**

The world's most expensive drug will not have its European Marketing Approval renewed in October 2017, just 5 years after it was first launched to treat Lipoprotein Lipase Deficiency (LPLD). The drug (Glybera; uniQure) cost > \$1.4 million for a single IV injection of LPL protein DNA in a viral capsid. In the entire time it has been available on the market, there has only been one single administration to a 40 year old woman. The primary culprit for low utilization was not only the cost, however it was the lack of efficacy data. With many new agents on the horizon, including Spark Therapeutics' SPK-RPE65 (inherited retinal disease) and Biomarin's BMN 270 (hemophilia), it will be interesting to see how the regulatory agencies adjust their data requirements and how payers will assess the value of these high-cost therapies.

Link for more information:



By: Dana Huettnermoser

### **Google's YouTube Losing Major Advertisers**

A growing number of major companies are suspending their marketing campaigns on Google's YouTube site. These companies include AT&T, Verizon, GlaxoSmithKline PLC, Enterprise Holdings Inc, McDonalds, PepsiCo and more. Advertising suspensions were in response to evidence that Google placed their ads on extremist YouTube videos. According to one Wall Street investment firm, this boycott of YouTube could cost as much as \$750 million in revenue.

Link for more information:



## CLINICAL UPDATE CORNER

*Hot Topics Impacting Healthcare and the Pharmaceutical Industry*



By: Bridget McGugan

### **Cannabidiol lowers frequency of drop seizures in Lennox-Gestaut syndrome (LGS)**

Adding cannabidiol (CBD) to antiepileptic drug (AED) therapy has been shown to reduce the frequency of drop seizures in patients with Lennox-Gestaut syndrome (LGS) in a phase III, placebo-controlled study. LGS is a rare type of epilepsy that is often refractory to traditional AEDs. LGS patients often have intellectual disabilities and face an increased risk of death compared to peers due to seizures and seizure-related falls. The precise mechanism of CBD in these patients is not completely understood, but the study showed that in 2 CBD cohorts, drop seizures were significantly reduced compared to placebo. Patients who received CBD 20 mg/kg/day saw a median reduction of 42% in drop seizure frequency, while patients who received CBD 10 mg/kg/day saw a median reduction of 37% in drop seizures. Patients in the placebo cohort saw a median reduction of 17% in drop seizure frequency.

### **Roche and Novartis Lose French Court battle over Off-Label use of Avastin in AMD**



By: Peter Chan

The case began in 2015 when French agencies approved reimbursement for Avastin's off-label use in wet age-related macular degeneration, even though two treatments were already available (Eylea, Lucentis). This was seen as a significant cost-saving measure, though the drug is not specifically formulated for intravitreal injection nor has Roche conducted trials in the AMD population. In March, the court battle Roche and Novartis fought against French authorities came to an end—Avastin will continue to be used and reimbursed in patients with wet AMD. This decision may decrease the incentives for drug companies to conduct additional trials to seek approval for new indications.

Link for more information:



### **FDA is limiting Codeine and Tramadol Use in Children**



By: Erin McGuire

On April 20<sup>th</sup>, the FDA issued a consumer alert warning parents that codeine and tramadol can cause dangerous breathing problems in children, as well as ordered label changes on prescription drugs which contain these ingredients. A few of the label changes include, a contraindication stating these ingredients should not be used to treat pain or cough (codeine) in children less than 12 years old and a strengthened warning to mothers, recommending not to breastfeed due to the risk of adverse reaction in infants. This alert and label changes affect 15 branded products as well as their generics. The FDA will continue to monitor the AE reports of medication containing these ingredients closely and take additional regulatory action if needed.

Link for more information:



### **How Pharma Companies Stack Up on Social Media**



By: Brielle Carramusa

This March, the social media analytics platform, Unmetric, released a report showing how pharma companies have stacked up against each other. They included 15 brands in their report and analyzed data from January 1<sup>st</sup> - December 30<sup>th</sup> 2016. Some highlights of the report include: Bayer wins with the highest reach, most impressions, and biggest fan base on Facebook and most mentions on Twitter. Merck had the highest growth rate of fan base on Facebook. AstraZeneca had the fastest responses to mentions on Twitter, but Eli Lilly was the most responsive to mentions. Roche had the most promoted posts, while Pfizer had the most organic posts. Bayer, Boehringer Ingelheim, and Novartis tied for the highest engagement score on Facebook. (Engagement score is a measure of interactions with community size factored in.)

Link for more information:



## WHO IS NEWEST FACE OF THE FDA?

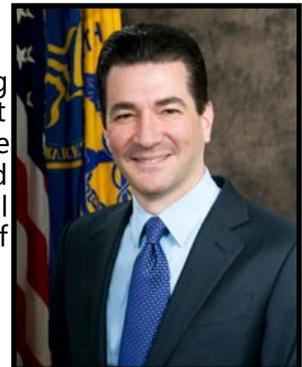
*An Insight Into Our Newly Appointed FDA Commissioner: Scott Gottlieb*

By: Eseoheh Osunde, Pharm.D.



### Professional Experience

Scott Gottlieb, M.D., is the newly appointed **23<sup>rd</sup> Commissioner** of the Food and Drug Administration (FDA) as of May 11, 2017. Dr. Gottlieb is a physician, a former resident fellow at American Enterprise Institute, a former Clinical Assistant Professor at the New York University School of Medicine in Manhattan, where he also practiced medicine. He completed a residency in internal medicine at the Mount Sinai Medical Center in New York, New York and is a graduate of the Mount Sinai School of Medicine and of Wesleyan University.



### Industry Interest

Dr. Gottlieb has an extensive professional history in the pharmaceutical industry working in both the public and private sectors. During his time at the FDA, he served as Deputy Commissioner for Medical and Scientific Affairs, 2005–07; Director of Medical Policy Development, 2004; and Senior Adviser to the Commissioner for Medical Technology, 2003–04.

In addition, Dr. Gottlieb has worked for some years as an adviser to pharmaceutical firms, and has served on boards of companies such as GlaxoSmithKline, Daiichi Sankyo and Tolero Pharmaceuticals.

### Position on FDA Policy

In his first speech to the staff as Commissioner, Dr. Gottlieb plans to tackle some challenges that will advance FDA's mission of "consumer protection and public health promotion"

- **Reduce Opioid Abuse:** He expressed a desire of "providing health care providers the tools to reduce exposure to opioids to only clearly appropriate patients"
- **Lower Drug Prices:** Faster approval of generics in order to "get more low cost alternatives to the market, to increase competition, and to give consumers more options"
- **Implement 21<sup>st</sup> Century Cures Act:** "Foster innovation and regulate areas of new technology but not raise cost of development"
- **Smoking Cessation:** "Move current smokers—unable or unwilling to quit—to less harmful products"
- **Food Safety:** Work with Center for Food Safety and Applied Nutrition (CFSAN) to execute a "new food safety framework"

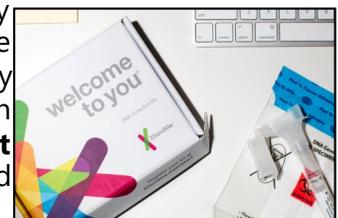


## GENETIC TESTING KIT FOR DISEASE RISK INFORMATION

By: Zarif Hakim, Pharm.D. Candidate Class of 2018

*Ernest Mario School of Pharmacy*

**2** 3andMe, previously known for their ancestry DNA kit, has received FDA approval for the first personal genetic testing kit designed to **assess ones risk for 10 genetic diseases**. This at home kit allows users to send a saliva sample to the company, who will identify specific genetic mutations that are associated with increased risk of various diseases. The 10 diseases include: Parkinson's disease, Celiac disease, Gaucher disease type 1, Late-onset Alzheimer's disease, Early-onset primary dystonia, Alpha-1 antitrypsin deficiency, Factor XI deficiency, Glucose-6-Phosphate Dehydrogenase deficiency, Hereditary hemochromatosis, and Hereditary thrombophilia. Previously, patients were only able to get their genetic information by visiting a medical professional or a genetic counselor. By giving consumers **direct access** to their genetic information, this product will allow users to make informed lifestyle choices and begin discussions with their healthcare provider.



# The Pawsletter

Furry Friends of Fellowship



**Name:** Blue (like the ice cream)  
**Hooman:** Clarice Lee  
**Breed:** Flemish Giant  
**DOB:** Feb 14, 2016

**Fav foods:** bananas, parsley, lettuce, carrots  
**Fav activities:** chasing flying curtains, digging tunnels  
**Fun facts:** I am almost 2 feet in length, weigh 11 lbs, and I am litter trained!!  
**Social Media:** IG @bluebunny214



**Name:** Kobe (like the beef)

**Hooman:** Christine Li  
**Breed:** part fantastic beast, part your guess is as good as mine

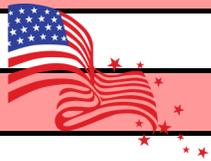
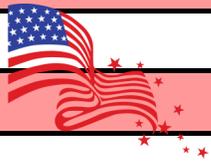
**DOB:** 11/12/13

**Fav foods:** stringed cheese, meat the redder the better

**Fun facts:** got legs longer than the less famous Kobe Bryant #ballislife

**Social media:** IG / snapchat: @kobeli8

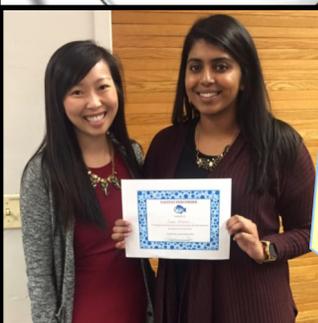
## Upcoming dates

Date	Event
June 18	Father's Day
June 30	RPIF Orientation 
July 4	Fourth of July 
July 13	First PDD!
July 14	ROPES Team Building 
August 3	NFL Pre-season begins 
Sept 1	Rutgers Scarlet Knights 1st football game

## 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!



Congrats to our March winner. **Ramya Mathew!**

For more information, please visit the RPIF webpage:

[http://pharmafellows.rutgers.edu/  
ifellows@pharmacy.rutgers.edu](http://pharmafellows.rutgers.edu/ifellows@pharmacy.rutgers.edu)

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 Christine.Li@Pfizer.com



Please contact us if you are interested in writing for the next edition of the *Fellowship Chronicles*.

Special thanks to all of our contributors!