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# RHO CHI *post*

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**An award-winning, monthly, electronic,  
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St. John's University College of Pharmacy and  
Health Sciences Rho Chi Beta Delta chapter**



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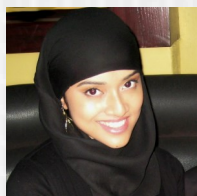
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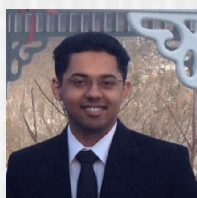
**@ Tasnima Nabi**  
6<sup>th</sup> Year, STJ; Editor-in-Chief

Writing has always been my greatest outlet for experience and knowledge, through which I hope to keep you engaged and informed. It is imperative to keep up with our changing profession and community. I look forward to bringing pertinent information to the newsletter.



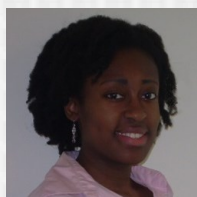
**@ Katharine Cimmino, PharmD**  
Graduate Copy Editor [Content-Focused]

I have always been an avid reader and writer. As a member of the Rho Chi Post I am able to merge my passions with the professionalism that comes with aspiring to be a healthcare provider. I am eager to be a part of a publication that promotes my interests and vocation.



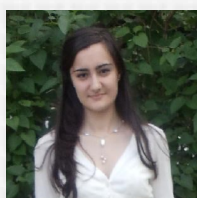
**@ Bharat Kirthivasan, PhD**  
Graduate Copy Editor [Content-Focused]

I received my doctorate in Industrial Pharmacy researching nanoparticles for delivery to the brain. The only thing I enjoy more than reading a well-written piece of work is writing it. I am glad to work for the Rho Chi Post, and I encourage others to do the same.



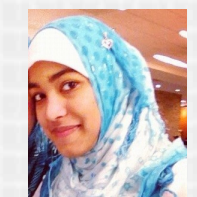
**@ Davidta Brown**  
5<sup>th</sup> Year, STJ; Copy Editor [Content-Focused]

My two great loves are innovative science and quality writing; the Rho Chi Post is an insightful combination of both. As an editor, I look forward to bringing relevant information and fresh perspectives to the student and faculty of St. John's University, as well as to making the Rho Chi Post a newsletter that offers something new to every reader.



**@ Tamara Yunusova**  
5<sup>th</sup> Year, STJ; Copy Editor [Content-Focused]

I enjoy articulating information in a captivating and insightful way. I hope to make this publication more informative, student-friendly, and innovative.



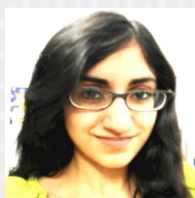
**@ Fatema Elias**  
6<sup>th</sup> Year, STJ; Copy Editor [Content-Focused]

I am honored to be a part of the Rho Chi Post team. In this age of technology and the continuously changing healthcare profession, I hope to engage like-minded students and professionals. Writing is something that I hold dear to my heart and I hope with this newsletter we can all stay well informed, interested, and educated.



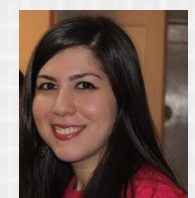
**@ Sang Hyo Kim**  
4<sup>th</sup> Year, STJ; Section Editor: Puzzles

Advancing technology and medicine, as well as prolonging the lifespan and improving quality of life, have increased the geriatric population. Pharmaceutical industries and healthcare systems persistently work to find solutions to changing demands and new problems of the society. I wish to learn, educate, and prepare myself and others for the future.



**@ Azia Tariq**  
5<sup>th</sup> Year, STJ; Section Editor: News

The Rho Chi Post is a prominent and highly esteemed resource for pharmacy students and professionals. I am privileged to be a part of the team and hope to contribute informative and engaging pieces to the newsletter.



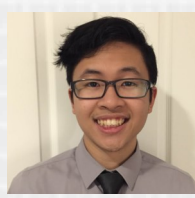
**@ Svetlana Akbasheva**  
6<sup>th</sup> Year, STJ; Section Editor: Clinical

I am very excited and honored to be part of the Rho Chi Post! In a profession that is constantly evolving with new developments, it is so important to remain informed and current. The Rho Chi Post helps do just that, and I look forward to contributing to this unique publication.



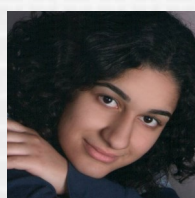
**@ Nicollette Pacheco**  
5<sup>th</sup> Year, STJ; Staff Editor [Graphics-Focused]

As a new member of the Rho Chi Post team, I have a vast appreciation of what it means to be a future pharmacist in the rapidly evolving world of healthcare. I am looking forward to being on the team as a graphics-focused staff editor, and I hope to bring my passion for science and creativity to the Rho Chi Post.



**@ Andrew Leong**  
6<sup>th</sup> Year, STJ; Staff Writer

Students have to do more than what is required of us in classes to truly learn about our profession. That's why I joined the Rho Chi Post. This publication represents a channel by which our team members, faculty, and readership can share information - something I believe is important in this ever-changing pharmacy world.



**@ Sylva Ohanian**  
5<sup>th</sup> Year, STJ; Staff Writer

The Rho Chi Post is a refreshing outlook on our profession. I am thrilled and grateful to be able to work with the other members in continuing its success, and hopefully to bring greater attention to it, which it deserves.



## RHO CHI POST: TEAM MEMBERS

**@ Fawad Piracha****6<sup>th</sup> Year, STJ; Finance and Outreach Manager**

I am delighted to join the editorial team. I have the firm intention of broadening readership and facilitating growth of the Rho Chi Post.

**@ Joshua Bliss****6<sup>th</sup> Year, STJ; Social Media Manager**

By providing student-organized, reliable healthcare information, the Rho Chi Post helps us all in fulfilling our education both in and out of the classroom. Education is the tool we use to set paths for our futures, and every chance to expand our education is a chance at building a better future. I am honored to be a part of the Rho Chi Post & look forward to the future!

We are always looking for  
creative and motivated  
students to join our team!

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## TABLE OF CONTENTS

<b>Even the FDA follows Kim!</b>	6
<i>By: Nancy Simon, PharmD Candidate 2016</i>	
<b>New Therapeutic Options for IBS-D</b>	9
<i>By: Benedette Cuffari, B.S. of Toxicology Candidate 2016</i>	
<b>Probiotics as a possible treatment antibiotic-associated diarrhea in the ICU</b>	10
<i>By: Holly Sokol, PharmD Candidate 2020</i>	
<b>Idiopathic Pulmonary Fibrosis: Treating a Mystery</b>	12
<i>By: Svetlana Akbasheva, Staff Editor</i>	
<b>Toxicology Crossword</b>	14
<i>By: Shane Salimnejad, PharmD Candidate 2016, University of Kansas</i>	
<b>Back Cover</b>	16

## QUOTE OF THE MONTH

*By: Nicollette Pacheco, Staff Editor [Graphics-focused]*





## Even the FDA follows Kim!

**By: Nancy Simon, PharmD Candidate 2016**

Many of you may have seen Kim Kardashian West's Instagram posts – most of which are 'selfies,' but recently, a particular post caught the attention of the Food and Drug Administration (FDA) this past August 2015. Kim posted a picture with Diclegis® (doxylamine succinate and pyridoxine hydrochloride), claiming that it has been the cure to her morning sickness. When it comes to promoting prescription drug products, it is great to state the benefits, but the risks must also be mentioned as per FDA regulations. None of the risks were mentioned in the social media post, which was additionally also posted on Twitter and Facebook—other social media outlets. The post includes a link to safety information, but that is not enough – the risks must be mentioned, thereby putting Duchesnay, Inc. at fault for not clearly listing all safety information in the drug advertisement posted by Kim. Diclegis® is manufactured by Duchesnay, Inc.—the company which prompted Kim with the exact advertisement she posted. They are at fault for not providing her all the necessary information. It is the responsibility of the drug manufacturer to make sure all efficacy and safety information are mentioned in any advertisements, including those posted on Instagram, Facebook, and Twitter.

The Office of Prescription Drug Promotion (OPDP) of the FDA reviewed the social media post this past August. The FDA filed a warning letter to Duchesnay, Inc. regarding the misbranding of Diclegis®<sup>2</sup>. The post also misbrands Diclegis® according to the Federal Food, Drug, and Cosmetic Act (FD&C Act).<sup>2</sup> This post is false or misleading due to the fact that it presents efficacy claims, but fails to state any risks associated with the drug.<sup>2</sup> Pharmaceutical companies sometimes allow celebrities to endorse their drugs, but it is the obligation of the drug company to include all pertinent information in the advertisement. Kim posted what was given to her and the Instagram post suggests that Diclegis® is safer than it has been demonstrated.<sup>2</sup> The Code of Federal Regulations, (CFR) Section 202.1 discusses regulations and violations of prescription-drug advertisements<sup>2</sup>. The CFR is the codification of the general and permanent rules published in the Federal Register by the depart-

ments and agencies of the Federal Government and this Instagram post infringes on the statutes set in place.<sup>1</sup>

Diclegis® contains doxylamine succinate, an antihistamine, and pyridoxine hydrochloride, which is also known as vitamin B6.<sup>5</sup> It is indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management.<sup>4</sup> Conservative management includes eating small meals throughout the day, and having bland foods in the morning, such as crackers. The limitations of the drug is that it has not been studied in women with hyperemesis gravidarum.<sup>3</sup> Hyperemesis gravidarum is a condition which consists of severe, persistent nausea and vomiting during pregnancy, often leading to weight loss.<sup>6</sup> Some other symptoms may consist of light-headedness, weakness, headaches, fainting, or constipation.<sup>6</sup> Diclegis® is contraindicated in women with hypersensitivity to the components of Diclegis® – doxylamine succinate, other ethanolamine derivative antihistamines, pyridoxine hydrochloride, or any inactive ingredient in the formulation.<sup>4</sup> Another contraindication is women, who were on any monoamine oxidase (MAO) inhibitors.<sup>5</sup> MAO inhibitors intensify and prolong the central nervous system effects of doxylamine–pyridoxine, such as drowsiness.<sup>4</sup> In a double-blind, randomized, multicenter trial, the only adverse reaction that occurred at an incidence of greater than or equal to 5% and at a higher incidence with doxylamine–pyridoxine as compared to placebo was somnolence.<sup>4</sup> Due to this side effect, women should not drive, operate heavy machinery, or participate in other activities that would need their full attention.<sup>5</sup> Regarding concomitant medical conditions, because doxylamine–pyridoxine has anticholinergic properties, it should be used with caution in women with asthma, increased intraocular pressure, narrow angle glaucoma, stenosing peptic ulcer, pyloroduodenal obstruction and urinary bladder-neck obstruction.<sup>4</sup> Anticholinergic properties of antihistamines include reducing the volume of bronchial secretions which can cause thickening and can result in obstruction of the respiratory tract. Also, women should not breastfeed while using doxylamine–pyridoxine,<sup>4</sup> due to the fact that it can pass into breast

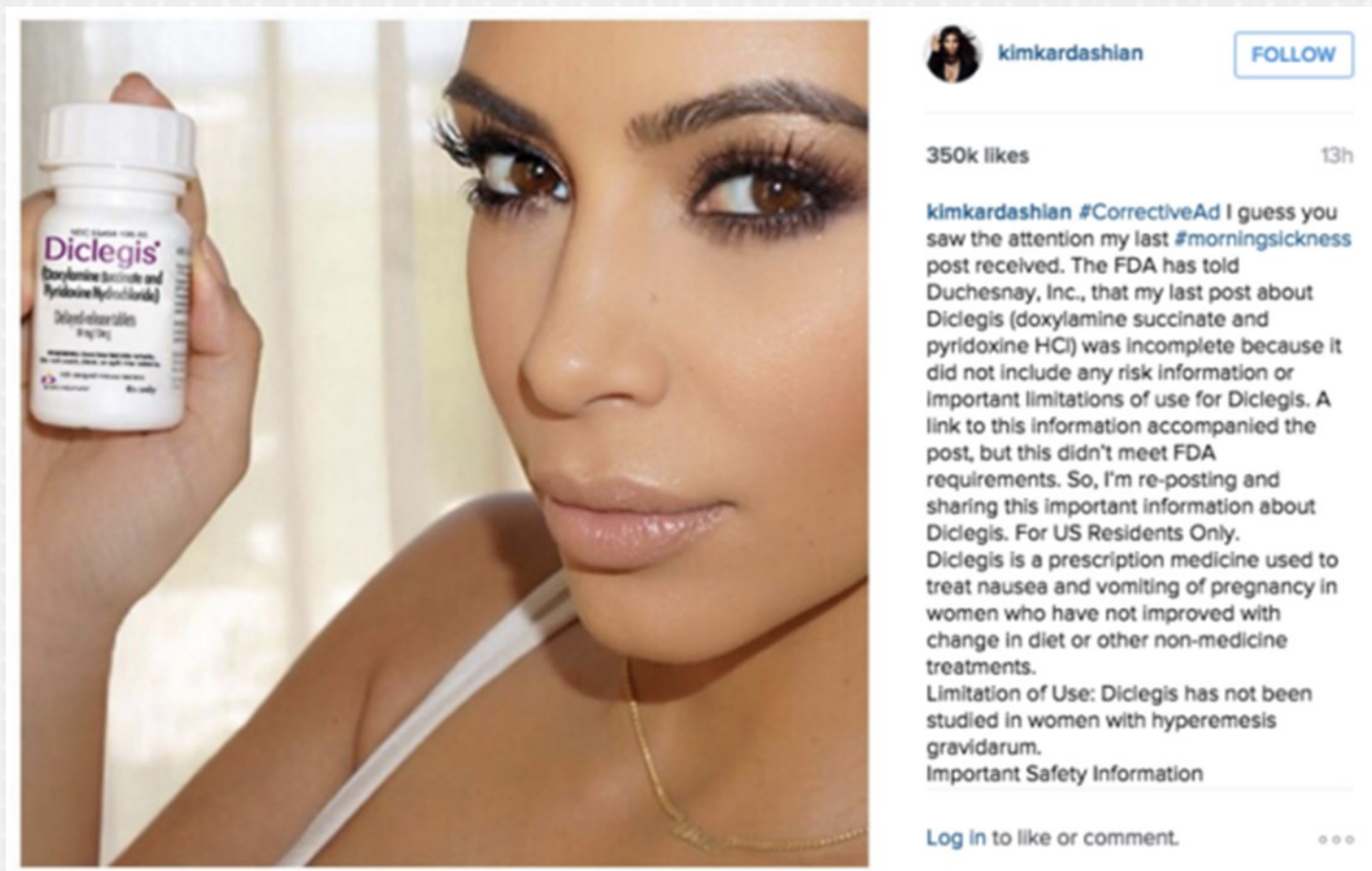
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milk and can cause harm to the baby.<sup>5</sup> These are some of the safety concerns with taking Diclegis®—none of which were mentioned on the Instagram post.

Duchesnay, Inc. should know the regulations when it comes to prescription drug advertising. Advertisements must have a balance of efficacy information as well as safety and risk information. Failure to mention any of the risks of Diclegis® allows patients to assume that the medication does not have a lot of safety risks. Duchesnay, Inc. received an untitled letter from the FDA back in 2013, due to an announcement letter OPDP had reviewed. The OPDP reviewed an announcement letter submitted by Duchesnay, Inc who alerted the general public regarding the approval of Diclegis®.<sup>7</sup> The letter also presented various efficacy claims, but failed to communicate risk information.<sup>7</sup> The letter states, “Today I am pleased to inform you that the U.S. Food and Drug Administration has approved Diclegis® indicated for the treatment of nausea and vomiting of pregnancy (NVP) in women who do not respond to conservative management. Millions of pregnant women could benefit from an approved NVP treatment and Diclegis® represents a much needed FDA-approved treatment option.”<sup>7</sup> The letter omitted all risk information, including the contrain-

dications, warnings and precautions, and the most frequently reported adverse event for Diclegis®.<sup>7</sup> The letter falsely suggests that Diclegis® is safer than has been demonstrated.<sup>7</sup>

The OPDP requested that Duchesnay, Inc. immediately stop misbranding Diclegis®. OPDP requested this after they released the announcement letter to the public, as well as when the Instagram post was released. The company was told to submit a written response replying to the warning letter, on or before August 21, 2015, stating whether they intend to comply with the FDA request. They were to list all promotional materials for Diclegis® that contain presentations such as those described in the warning letter and explain their plan for discontinuing use of such materials, or cease distribution of Diclegis® itself.<sup>2</sup> Because Duchesnay, Inc. has repeated serious violations, the FDA wants a comprehensive plan of action from them.<sup>2</sup> To clearly identify the violative promotional piece and focus on the corrective message, the OPDP recommended that the corrective piece include a description of the violation, provide information to correct the violation, and corrective messaging should be distributed using the same media, and generally for the same duration of time and with the same frequency that the violative promo-





tional material was distributed.<sup>2</sup> As per request, in late August, Duchesnay, Inc. issued a corrective advertisement via Instagram fixing their mistake. Besides the violations discussed in the warning letter, Duchesnay, Inc. is responsible to ensure that any distribution of Diclegis® complies with each applicable requirement of the FD&C Act and FDA regulations.<sup>2</sup>

All pharmaceutical companies are held accountable for accurately depicting the efficacy as well as the toxicity of their drug products through any promotional advertising they may have. Duchesnay, Inc. is fully responsible for stating facts regarding their product, Diclegis®. It is legally and ethically not right for pharmaceutical companies to misinform patients of the benefits, and especially the risks associated with any drug.

#### **SOURCES:**

1. Code of federal regulations (annual edition). U. S. Government Publishing Office Web Site. <http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR>. Accessed August 22, 2015.
2. Dean RT. Duchesnay, Inc. warning letter. U.S. Food and Drug Administration Web Site. <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM457961.pdf>. Published August 7, 2015. Accessed August 22, 2015.

3. Diclegis. <https://www.diclegis.com/en/>. Published 2013. Accessed August 22, 2015.

4. Diclegis® (doxylamine succinate and pyridoxine hydrochloride) [Package Insert]. Bryn Mawr, PA; Duchesnay USA, Inc.; 2013.

5. Diclegis patient information. [https://www.diclegis.com/pdf/Diclegis\\_Patient\\_Information.pdf](https://www.diclegis.com/pdf/Diclegis_Patient_Information.pdf). Published April, 2013. Accessed August 22, 2015.

6. Hyperemesis gravidarum. <https://www.nlm.nih.gov/medlineplus/ency/article/001499.htm>. Last updated August 16, 2014. Accessed August 22, 2015.

6. Newcomer CA, Thompson TN. Duchesnay, Inc. Untitled Letter. U.S. Food and Drug Administration Web Site. <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm376300.pdf>. Published November 12, 2013. Accessed August 22, 2015.

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## New Therapeutic Options for IBS-D

By: **Benedette Cuffari, B.S. of Toxicology Candidate 2016**

Affecting 10%-15% of the population in Western countries, irritable bowel syndrome (IBS) is most often categorized by altered bowel habits involving chronic or recurrent diarrhea or constipation.<sup>1</sup> IBS patients with chronic diarrhea, sometimes referred to as IBS-D, exhibit abdominal pain and/or discomfort in addition to loose or watery stools. Current treatment options for IBS-D are limited and include antispasmodics, antidepressants, antidiarrheal agents, and alosteron.<sup>2</sup> IBS-D can be quite disabling for some patients, and the current treatment options are not effective for everyone. Recently, the FDA has approved two new therapies, eluxadoline (Viberzi®) and rifaximin (Xifaxan®), to treat IBS-D in adult men and women.<sup>1</sup>

The gastrointestinal tract contains  $\mu$ ,  $\delta$ , and  $\kappa$  opioid receptors, which all play a key role in regulating gastrointestinal motility, secretion, and visceral sensation.<sup>2</sup> Eluxadoline interacts with these opioid receptors in two ways to treat acute diarrhea. As a  $\mu$ -opioid receptor agonist, eluxadoline slows gastrointestinal transit, and as a  $\delta$ -opioid receptor antagonist, this drug acts as an analgesic agent, alleviating some of the abdominal pain that often accompanies diarrhea in IBS-D.<sup>2</sup> The FDA has evaluated several phases of trials testing the efficacy of eluxadoline in both *in vitro* and *in vivo* studies. *In vitro* showed that eluxadoline reduces intestinal contractility and inhibits neurogenically mediated secretion, while *in vivo* studies showed a reduction in gastrointestinal transit and fecal output in stressed and nonstressed mice.<sup>2</sup>

In a pair of phase III, randomized, double-blind, placebo controlled studies, patients receiving eluxadoline reported experiencing a greater relief of their IBS symptoms than placebo patients. These studies involved a combined total of 2,427 patients who were randomized to receive a twice-daily treatment with either eluxadoline at 75 or 100 mg, or the placebo, for a duration of 12 weeks in one study and 26 weeks in the other.<sup>3</sup> 29% of patients taking 100 mg of eluxadoline b.i.d. during the trials reported that more than 75% of their days were urgency free, compared to 12% of patients on placebo.<sup>3</sup> 43.2% of patients taking 100 mg of eluxadoline also experienced a 40%-50% mean reduction in daily abdominal pain scores, compared with 34.8% of the control patients.<sup>3</sup>

Some recent studies have also suggested that pa-

tients with IBS may have an alteration in their gastrointestinal flora, particularly bacterial overgrowth in the small intestine. Small intestinal bacterial overgrowth (SIBO) can cause excessive gas production and intestinal malabsorption that can result in diarrhea, bloating, abdominal pain, and/or constipation.<sup>4</sup> Rifaximin has gastrointestinal-specific antibiotic effects that prevent SIBO. This effect against SIBO prevents the mucosal inflammation, impaired intestinal barrier function, and visceral hyperalgesia in response to chronic stress that is often associated with IBS-D.<sup>5</sup> Compared to other antibiotics that relieve the symptoms of SIBO, such as neomycin and  $\beta$ -lactams, rifaximin showed efficacy with fewer side effects.<sup>6</sup> Rifaximin is a particularly desirable treatment option for bacterial IBS-D because of its lengthy residence time in the colon and its minimal systemic absorption.

The study of rifaximin for IBS-D was conducted in two double-blind, placebo-controlled, parallel trials designated as TARGET1 and TARGET 2, in which 600 IBS-D patients took either a 550 mg dose of rifaximin or a placebo three times a day for two weeks.<sup>7</sup> Patients were followed for 10 weeks after the 2-week study period, during which time 40.7% of patients receiving rifaximin experienced relief of global IBS symptoms, compared to 31.7% of placebo patients claiming similar relief.<sup>7</sup>

One of the biggest problems in treating IBS-D is the lack of understanding of the exact pathology of this disease. As scientists continue to persevere toward understanding the complexity of this debilitating illness, more treatment options are emerging in order to improve the quality of life of these patients. The approval of eluxadoline and rifaximin will hopefully provide more patients with a promising future in maintaining a healthy and comfortable life with IBS-D.

### SOURCES:

1. U.S. Food and Drug Administration. FDA approves two therapies to treat IBS-D. U.S. Food and Drug Administration Web Site. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm448328.htm>. Published 27 May 2015. Last updated 28 May 2015. Accessed 4 August 2015.
2. Dove LS, Lembo A, Randall CW, et al. Eluxadoline benefits patients with irritable bowel syndrome with diar-

rhea in a phase 2 study. *Gastroenterology*. 2013; 145(2):329-38.e1. doi: 10.1053/j.gastro.2013.04.006.

3. Jancin B. Eluxadoline scores in phase III trial for IBS. *GI & Hepatology News*. 2014; 8(7):17. [https://m.gastro.org/journals-publications/gi-hepatology-news/GI\\_-Hepatology\\_News\\_-\\_July\\_2014.pdf](https://m.gastro.org/journals-publications/gi-hepatology-news/GI_-Hepatology_News_-_July_2014.pdf).

4. Saadi M, and McCallum RW. Rifaximin in irritable bowel syndrome: rationale, evidence and clinical use. *Ther Adv Chronic Dis*. 2013; 4(2): 71-5. doi: 10.1177/2040622312472008

5. Xu D, Gao J, Gilliland M 3rd, et al. Rifaximin alters

intestinal bacteria and prevents stress-induced gut inflammation and visceral hyperalgesia in rats. *Gastroenterology*. 2014; 146(2):484-96. doi: 10.1053/j.gastro.2013.10.026.

6. Basseri RJ, Weitsman S, Barlow GM, Pimental M. antibiotics for the treatment of irritable bowel syndrome. *Gastroenterol Hepatol*. 2011; 7(7):455-93.

Pimentel M, Lembo A, Chey WD, et al. Rifaximin therapy for irritable bowel syndrome without constipation. *N Engl J Med*. 2011; 364(1):22-32. doi: 10.1056/NEJMoa1004409.

## Probiotics as a possible treatment antibiotic-associated diarrhea in the ICU

By: Holly Sokol, PharmD Candidate 2020

Antibiotic-associated diarrhea (AAD) can occur due to antibiotics changing the elements of the gut and thereby, increasing an organism's inhabitation. Diarrhea is common in as many as 40% of critically ill patients. An even greater problem is *Clostridium difficile* (antibiotics-associated) becoming a leading cause of mortality in hospital-related infections.<sup>1</sup> Probiotics help prevent *C. difficile* infection in small scale studies; however, the results are still unclear in large-scale studies.<sup>1</sup>

Studies have shown that probiotics are safe to use in AAD patients.<sup>2</sup> Probiotic use in AAD patients has increased with access to over-the-counter products.<sup>1</sup> After reviewing 16 studies and 3400 patients, a Cochrane Review determined *Lactobacillus rhamnosus* GG and *S. boulardii* to be effective probiotics in preventing AAD.<sup>3</sup> In a single-center, randomized, double-blind, placebo-controlled dose-ranging study by Gao et al, hospitalized adult-patients were treated with a probiotic containing 50 billion colony-forming units of *Lactobacillus*.<sup>4</sup> Patients that received two capsules daily had a lower incidence of AAD (15.5%) than patients who received only one capsule (28.8%) or placebo (44.1%).<sup>4</sup>

*C. difficile* is a major cause of infectious diarrhea;

overgrown bacteria release toxins that attack the lining of the intestines. Studies of probiotic use and *C. difficile* have shown inconsistent results. In a four-week randomized placebo-controlled trial after antibiotic therapy, *S. boulardii* (500 mg twice a day) reduced *C. difficile*-associated diarrhea (CDAD) recurrence rates.<sup>3</sup> The objective of the study was to determine the safety and efficacy of a new combination treatment for patients with CDAD. Patients were randomized to *S. boulardii* or placebo after treatment with an antibiotic (vancomycin hydrochloride or metronidazole).<sup>5</sup> Patients treated with *S. boulardii* had a significantly lower relative risk of CDAD recurrence ( $p=.04$ ) compared with placebo ( $p=.86$ ).<sup>5</sup>

However, there are several studies that fail to show benefit with probiotic treatment. The Placide study examined patients over the age of 65 who were not in an intensive care unit and who lacked a history of *C. difficile* infection. In the study, patients took two strains of *Lactobacillus* and two strains of bifidobacteria for 21 days through a microbial preparation. The patients were previous only oral or intravenous antibiotics. After eight weeks, there was no significant difference between the probiotic and placebo groups. While the medication was

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designed to make the patient better they received adverse side effects such as bloating (as an increase in 3-fold).<sup>1</sup> It is unclear if the solution is to bind the gut with another strain of bacteria.<sup>1</sup> In a systematic review, the efficacy of probiotic intervention in prevention of CDAD in older patients was evaluated. Among the six randomized control trials, 3562 patients 65 years or older were treated with various probiotic strains including *Lactobacillus*, *Bifidobacterium*, *Saccharomyces*, *Streptococcus*, *Enterococcus* and *Bacillus*.<sup>6</sup> The systematic review found that none of the probiotics were effective in prevention of CDAD in older patients.

Due to the inconsistent results of trials, specialists feel probiotics are not completely effective. Paul Wischmeyer, MD, a critical care expert at the University of Colorado School of Medicine, Anschutz Medical Campus, Aurora, believes the flaw was not the probiotic itself, but the way it was delivered.<sup>2</sup> After results from the PRObiotics in PANcreatitis TRIal were publicized, in which probiotic bacteria was introduced in the small bowel and resulted in the death of eight people, data proved that probiotics should be distributed through the mouth and not directly through the gastrointestinal tract. Dr. Esaian, PharmD, BCPS, a pharmacotherapy specialist, critical care at the New York University Langone Medical Center, New York City, is hesitant to recommend probiotics to her critically ill patients because of the limited data available on agents.<sup>2</sup> Although results have varied, risk vs. benefit analysis ultimately depends on clinician practice and patient preferences.

#### SOURCES:

1. Johnson D. Probiotics: help or harm in antibiotic-associated diarrhea?. Medscape. [http://www.medscape.com/viewarticle/830002#vp\\_3](http://www.medscape.com/viewarticle/830002#vp_3). Published 09/10/2014. Accessed 02/24/2015.
2. Rosenthal M. Probiotics for antibiotic-associated diarrhea in the ICU? Jury still out. *pharmacypracticenews*. [http://www.pharmacypracticenews.com/ViewArticle.aspx?d=Web+Exclusives&d\\_id=239&i=January+2015&i\\_id=1141&a\\_id=29290](http://www.pharmacypracticenews.com/ViewArticle.aspx?d=Web+Exclusives&d_id=239&i=January+2015&i_id=1141&a_id=29290). Published 01/21/2015. Accessed 02/24/2015.
3. Ciorba M. A gastroenterologist's guide to probiotics. Medscape. [http://www.medscape.com/viewarticle/770468\\_4](http://www.medscape.com/viewarticle/770468_4). Published 10/09/2012. Accessed 03/28/2015
4. Gao XW, Mubasher M, Fang CY, Reifer C, Miller LE. Dose-response efficacy of a proprietary probiotic formula of *Lactobacillus acidophilus* CL1285 and *Lactobacillus casei* LBC80R for antibiotic-associated diarrhea and *Clostridium difficile*-associated diarrhea prophylaxis in adult patients. *Am J Gastroenterol*. 2010;105(7):1636-41. doi: 10.1038/ajg.2010.11
5. McFarland LV, Surawicz CM, Greenberg RN, et al. A randomized placebo-controlled trial of *Saccharomyces boulardii* in combination with standard antibiotics for *Clostridium difficile* disease. *JAMA*. 1994;271(24):1913-8.
6. Xie C, Li J, Wang K, Li Q, Chen D. Probiotics for the prevention of antibiotic-associated diarrhea in older patients: A systematic review. *Travel Med Infect Dis*. 2015;13(2):128-134. doi: 10.1016/j.tmaid.2015.03.001

## Idiopathic Pulmonary Fibrosis: Treating a Mystery

**By: Svetlana Akbasheva, Section Editor**

Idiopathic pulmonary fibrosis (IPF) is a devastating condition in which the lungs become thick and tough with scar tissue and progressively lose their ability to efficiently deliver oxygen to the blood.<sup>1</sup> That the disease has no established cause can make diagnosis difficult. However, the 2011 ATS/ERS/JRS/ALAT guidelines<sup>2</sup> provide three criteria to establish a diagnosis of IPF. First, all other causes of interstitial lung disease must be excluded. These include environmental exposures, certain medications, and connective tissue diseases.<sup>2</sup> While there is no standardized or validated approach to conduct such a diagnosis of exclusion, a thorough physical assessment and patient history are essential.<sup>2</sup> Physicians also need to perform a multitude of diagnostic tests to evaluate the extent of lung damage and rule out other diseases like cancer and tuberculosis.<sup>1</sup> The second diagnostic criterion set out by the guidelines is the presence of a usual interstitial lung disease pattern, or UIP, on high-resolution computed tomography (HRCT). Thirdly, if a lung biopsy is performed, the combined findings of the biopsy and HRCT should have a pattern consistent with IPF.<sup>2</sup>

The worldwide prevalence of IPF is estimated to be between 13 and 20 cases per 100,000 people.<sup>3</sup> It is usually diagnosed in the older population—largely people in their 60s and 70s—and affects men more than women.<sup>1</sup> Although the cause of IPF is unknown, several risk factors are suspected based on the characteristics of patients who present with the disease. Cigarette smoking is thought to be one of the biggest risk factors; others include environmental exposures and microbes.<sup>2</sup> Since many patients with IPF have comorbid GERD, it is hypothesized that aspiration of acid droplets into the lungs may prompt lung damage in this manner.<sup>1</sup> In addition, less than 5% of patients with IPF have a close family member with the disease, suggesting that some cases may involve a genetic component.<sup>2</sup> So far two genes have been potentially implicated in the pathology of this disease, known as *TERC* and *TERT*, which are involved in making the telomerase enzyme. Although more research is needed, it is hypothesized that genetics may predispose certain people to IPF but environmental factors are necessary to ultimately precipitate the disease.<sup>3</sup>

Generally, patients with IPF first present with shortness of breath and a dry, hacking cough. Signs and

symptoms can also include fatigue, unintended weight loss, shallow breathing, and clubbing of the fingers and toes.<sup>1</sup> Without treatment, pulmonary function gradually deteriorates and patients usually survive for no more than five years after diagnosis. The majority of patients die from respiratory failure or disease complications such as pulmonary hypertension, pulmonary embolism, heart failure, or pneumonia.<sup>1</sup> There is no cure for IPF, and until recently there were no effective pharmacological treatments available for this condition.<sup>1,2,4,5</sup>

The 2011 IPF treatment guidelines were written before the approval of two medications for IPF in 2014. In the absence of effective treatment for IPF, the recommendations for drug therapy were strongly against the use of agents such as corticosteroid monotherapy, colchicine, and cyclosporine A, while weakly supportive of the use of an acetylcysteine/ azathioprine/ prednisone combination, acetylcysteine monotherapy, anticoagulants, and pirfenidone. These were international guidelines, and pirfenidone had not yet been approved in the United States. The only strong recommendations made by the guidelines were for long-term oxygen therapy and lung transplantation in appropriate patients.<sup>2</sup> Although lung transplantation prolongs survival in advanced disease, only about 44% of IPF patients survive for five years after the procedure.<sup>6</sup> Pulmonary rehabilitation can be used as adjunctive therapy in all stages of IPF; it educates patients about managing their disease by teaching them techniques to conserve energy and improve breathing. Providing access to counseling or support groups is also encouraged.<sup>1</sup>

On October 15, 2014, the FDA approved nintedanib (Ofev®), and pirfenidone (Esbriet®), the first two medications indicated exclusively for IPF.<sup>4,5</sup> Based on the findings of clinical trials, these agents have been proven to slow IPF progression.<sup>4,5</sup> While nintedanib works through the inhibition of tyrosine kinases,<sup>7</sup> the mechanism of action of pirfenidone is unknown.<sup>8</sup> Both are oral medications, although pirfenidone has a higher pill burden (three capsules three times a day)<sup>8</sup> than nintedanib (one capsule twice daily).<sup>7</sup> In addition, both have warnings regarding the elevation of liver enzymes.<sup>7,8</sup> It will be interesting to see long-term safety and efficacy data for these two medications in the future, as well as changes in the guidelines in response to the availability of these agents.



**SOURCES:**

1. Idiopathic pulmonary fibrosis. National Heart, Lung, and Blood Institute. <http://www.nhlbi.nih.gov/health/health-topics/topics/ipf>. Updated 09/20/11. Accessed 05/15/15.
2. Raghu G, Collard HR, Egan JJ, et al. An official ATS/ERS/JRS/ALAT statement: idiopathic pulmonary fibrosis: evidence-based guidelines for diagnosis and management. *Am J Respir Crit Care Med*. 2011;183(6):788-824.
3. Idiopathic pulmonary fibrosis. Genetics Home Reference. <http://ghr.nlm.nih.gov/condition/idiopathic-pulmonary-fibrosis>. Updated April 2015. Accessed September 20, 2015.
4. FDA approves Ofev to treat idiopathic pulmonary fibrosis. Food and Drug Administration. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm418994.htm>. Updated October 16, 2014. Accessed May 15, 2015.

5. FDA approves Esbriet to treat idiopathic pulmonary fibrosis. Food and Drug Administration. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm418991.htm>. Updated October 16, 2014. Accessed May 15, 2015.
6. King TE, Pardo A, Selman M. Idiopathic pulmonary fibrosis. *The Lancet*. 2011; 378(9807):1949-61.
7. Ofev (nintedanib) [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; October 2014.
8. Esbriet (pirfenidone) [package insert]. Brisbane, CA: InterMune, Inc.; October 2014.

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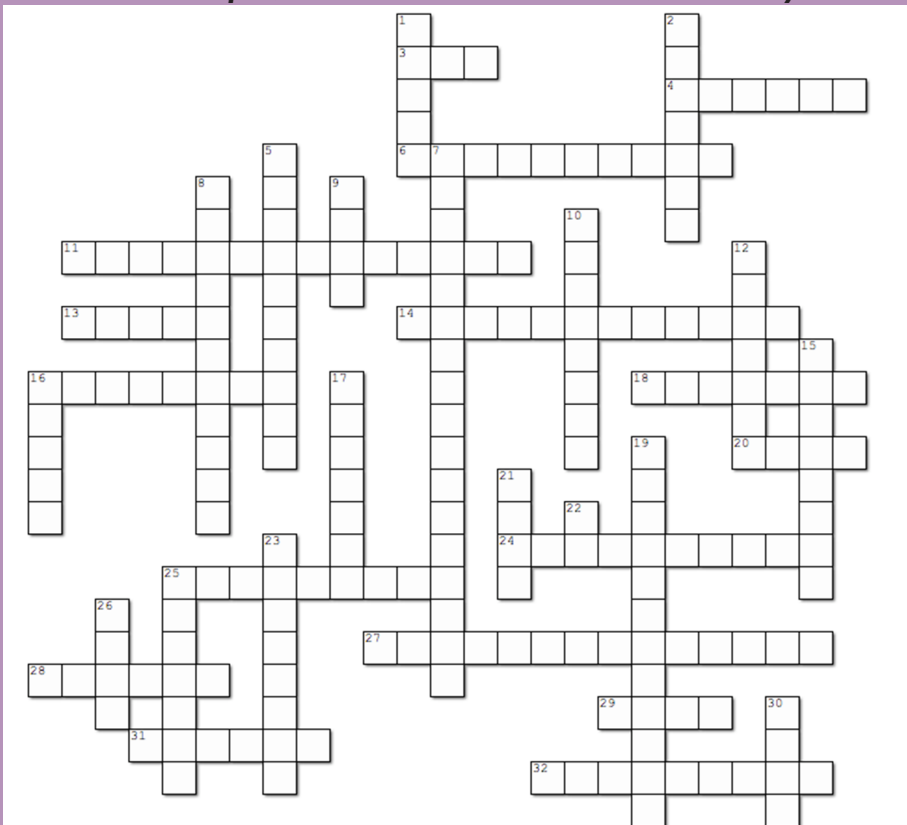
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## PUZZLES

# TOXICOLOGY | CROSSWORD

By: *Shane Salimnejad, PharmD Candidate 2016, University of Kansas*



### ACROSS

3. Initial Management
4. Chasing the dragon
6. Long acting opioid antagonist
11. Can lead to Torsades de pointes
13. Red man poster child
14. Tingling feeling
16. Wrinkle free
18. Protamine sulfate reverses
20. N-acetyl cysteine reverses
24. MTX rescue
25. Flush down your toilet
27. Major diarrhea culprit of Augmentin
28. Pinpoint pupils
29. No monitoring, no reversal agent
31. Yellow fruit; alcohol withdrawal
32. Mofenson & Greensher term

### DOWN

1. Chemical warfare
2. Delays methanol metabolism
5. Anticholinergic effect, oral cavity
7. Santa's gift to naughty kids
8. Irreversible aminoglycoside toxicity
9. Tetrodotoxin
10. Grape sugar
12. NOAC susceptible to dialysis
15. Factors II, VII, IX, X depend on
16. Parenteral K criterion
17. EtOH + \_\_\_\_\_ = benzoylethylecgonine
19. Decreased blood pH, alcoholics and diabetics
21. Green leafy smoothie
22. Analgesia receptor
23. Respiratory depression reversal agent
25. Digoxin reversal
26. This med and aged cheese don't mix
30. Molly, not Ringwald

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## PUZZLES: ANSWERS

**Across:**

- 3. ABC
- 4. Heroin
- 6. Naltrexone
- 11. QT Prolongation
- 13. Vanco
- 14. Parasthesias
- 16. Botulism
- 18. Heparin
- 20. APAP
- 24. Leucovorin
- 25. Duragesic
- 27. Clavulanic acid
- 28. Miosis
- 29. NOAC
- 31. Banana
- 32. Toxidrome

**Down:**

- 1. Sarin
- 2. Ethanol
- 5. Xerostomia
- 7. Activated charcoal
- 8. Ototoxicity
- 9. Fugu
- 10. Dextrose
- 12. Pradaxa
- 15. Vitamin K
- 16. Bleed
- 17. Cocaine
- 19. Ketoacidosis
- 21. Kale
- 22. Mu
- 23. Naloxone
- 25. Digifab
- 26. MAOI
- 30. MDMA

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