



International Foundation for  
Functional Gastrointestinal Disorders

**IFFGD**

*Information. Assistance. Support.*

# DigestiveHealth Matters

Participate in your own health care | Vol. 23, No. 1, © 2014 IFFGD

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**Your IBS goes wherever you go.  
Shouldn't you have reliable  
information anywhere you go, too?**



**Download the  
free IBS mobile app  
from IFFGD, and have  
trustworthy information  
at your fingertips.**



**April is IBS  
Awareness Month**

*[www.aboutIBS.org](http://www.aboutIBS.org)*

Irritable bowel syndrome (IBS) is characterized by abdominal pain or discomfort associated with a change in bowel habit (diarrhea and/or constipation). Other symptoms may also occur. Talk to your doctor if you experience symptoms. The first step to treatment is a confident diagnosis.

# Marking 2014 IBS Awareness Month with Launch of Mobile App

In recognition of IBS Awareness Month in April, we launched a new mobile app, providing educational information about irritable bowel syndrome (IBS). The mobile app, titled *IBS Info*, provides reliable information from leaders in the GI field to help individuals better understand the symptoms, causes, and treatments of IBS.

The new app can be downloaded in the Apple Store for use on iOS and at Google Play for Android platforms. Topics covered include food and diet, tips on working with your doctor, and guidance on daily living with the disorder.

IBS is a chronic digestive condition characterized by recurring abdominal pain or discomfort. The pain is associated with a change in bowel pattern, such as constipation and/or diarrhea.

In addition to constipation or diarrhea, the following symptoms may accompany IBS:

- Heartburn
- Nausea
- Abdominal fullness
- Bloating
- Feelings of urgency to use the restroom
- Feeling of an “incomplete” bowel emptying
- Fatigue
- Muscle pain
- Sexual dysfunction
- Headache

“More and more people are using the internet and their smartphones to access information to help manage their health. With IBS the sheer amount of information can be overwhelming, not to mention the complexity of the condition. Our new app is a place where people can know that what they are reading is trustworthy.”

— Nancy J. Norton, president and founder of IFFGD



Those with the condition can experience symptoms that change over time or vary from day to day, and many times, symptom flare ups come on unexpectedly. The symptoms, coupled with the uncertainty and fluctuation, can significantly impair the quality of life for those that are affected.

About one of every 10 people is affected by IBS, including a growing number of returning military personnel. IFFGD first designated IBS Awareness Month in April of 1997 as a time to raise awareness and educate people on the symptoms and prevalence of the disorder. If you or someone you know is experiencing the symptoms of IBS, see your health care provider.



## Changes You Should Not Ignore if You Have IBS

The symptoms of irritable bowel syndrome (IBS) can be hard to manage. Symptom episodes may continue to interfere with normal activities well after an initial diagnosis and treatment. That can be discouraging and a cause of worry. It's reassuring to know that having IBS does not put you at an increased risk of developing other digestive disorders or diseases.

Despite this, there are times when it may be best for your doctor to review your symptoms and how they affect you. Here are suggestions for when to seek additional guidance from a medical professional.

### Developments of Concern

Wrong beliefs about IBS may lead to distress, more doctor visits, and unneeded tests. It helps to know, IBS:

- Does *not* cause physical damage
- Does *not* increase the risk of colon cancer, inflammatory bowel disease, diverticulitis, or other gut disorders

On the other hand, neither does IBS protect you from acquiring these conditions. It also can coexist with another disorder.

Two situations provide alerts that another disease might be present:

- The presence of an “alarm” symptom
- Increased personal risk

**Alarm Symptoms** – An “alarm” symptom, sometimes also called a “red flag,” simply means a symptom *not* explained by IBS, which calls for additional investigation. These are symptoms and signs of an underlying disease that physically damages the gut.

Sometimes the most alarming of such symptoms, namely bleeding, turns out to be un-alarming after all, but you should always let your doctor know. Small amounts of bright red blood usually turn out to be from a hemorrhoid or small tear (fissure) in the anal passage. Rarely, it could be due to another condition that requires treatment. On the other hand, large amounts of red blood or black, tarry colored stool calls for urgent medical attention.

Here are some typical signs that call for special attention:

- New symptom onset at age of 50 or older
- Blood in the stools
- Nighttime symptoms that wake you up
- Unintentional weight loss
- Change in your typical IBS symptoms (like new and different pain)
- Recent use of antibiotics
- Family history of other GI diseases, like cancer, inflammatory bowel disease, or celiac disease

**Increased Personal Risk** – Sometimes there is a factor in your life that may put you at greater than average risk of acquiring a serious intestinal disease. For example, if a parent or sibling has had colon cancer or even a precancerous

colonic polyp, then your risk of polyps is greater than normal. Inflammatory bowel disease (ulcerative colitis and Crohn's disease) tends to occur in families. Celiac disease, where essential nutrients fail to be absorbed, has its greatest prevalence among the descendants of people born in Northern Europe.

IBS patients are as likely as anyone to suffer an intestinal infection, which may add to and confuse the symptoms. You should be suspicious of an infection if:

- You have been traveling to tropical or developing parts of the world
- Friends and family are infected
- You have been exposed to possibly contaminated drinking water

Let your doctor know about any of these concerns.

### When to See your Doctor

IBS follows an unpredictable course. There may be periods of relative calm, mixed back and forth with periods of pain or discomfort and chaotic bowel habit that interfere with your life. However, if the basic pattern of your bowel symptoms changes, or one of the situations described above occur, a visit to your doctor is in order.

Sometimes a drug you are taking for another purpose or something new in your diet may be responsible for the change, and your doctor can help you determine that. A visit also provides your doctor with the opportunity to review your diet, exercise habits, and drug regimen, and perhaps recommend changes.

### Putting it all Together

IBS is long-term (chronic) and tends to repeatedly come and go over time. It does not predispose you to other GI disease. However, IBS does not protect you from the new onset of other disease. New and different symptoms may make you suspicious that something new is happening.

You should visit your doctor if you become aware of alarm symptoms or of a factor that might put you more than normally at risk of another disease. Your doctor may review your symptoms and perhaps perform certain tests.

Usually, if the original diagnosis was sound, recurrent, but similar symptoms do not signify a new disease.

Adapted from IFFGD publication 247, *Changes You Should Not Ignore if You Have IBS*, by W. Grant Thompson, M.D.



## Fiber Therapy in IBS and other GI Disorders

Irritable bowel syndrome (IBS) is one of the most common and troublesome conditions for which individuals seek medical attention. Specific food practices may contribute to symptoms of constipation, diarrhea, bloating, gas, and abdominal pain. Adding fiber to your diet may help improve bowel function and decrease symptom severity.

Fiber is a double-edged sword for people with intestinal disorders. While fiber alleviates constipation, certain high fiber foods, such as bran, may increase gas production and bloating. However, it seems likely that most people with IBS will benefit from at least a moderate increase in dietary fiber intake.

While fiber may appear to be a simple solution, the typical Western diet for adults often falls below the current recommendation of 20–35gm per day. Adding too much fiber too fast can result in a worse condition than being on a low fiber diet. A *gradual* increase in dietary fiber can modify, improve and, in some people, eliminate the abnormal bowel habits and painful symptoms associated with IBS. People who have difficulty obtaining the goal of 20–35gm per day through diet alone may find fiber supplementation helpful. With any dietary fiber, the guideline is to *start low, go slow*.

As an added benefit, consuming generous amounts of fiber in your everyday diet potentially can improve overall health. Fruits and vegetables appear to exert a strong healthy effect.

### Gastrointestinal (GI) Health Benefits of Dietary Fiber

Dietary fiber has specific benefits for maintaining GI health. High fiber foods take longer to chew, which gives the brain a chance to register fullness, preventing overeating. High fiber foods also slow digestion, which prolongs this feeling of fullness.

Research in fiber and GI health took off in the 1970s when a link was first proposed between high fiber intake and low rates of some chronic diseases. While the use of dietary fiber in the treatment of certain GI disorders may be debatable, the evidence to at least consider fiber therapy is strong.

IBS patients who are prone to constipation appear to benefit the most from fiber treatment. Other people with various forms of GI disorders may benefit from a variety of treatments involving more than a little trial and error. Because these disorders have many components, the greatest challenge will be in identifying one or several strategies that prove effective.

### Soluble and Insoluble Fiber

Dietary fiber can be classified as either soluble or insoluble. Soluble fiber dissolves in water, becomes a soft gel, and is readily fermented. These include pectin, guar gum, and other gums. Insoluble fiber does not dissolve or gel in water and is poorly fermented. Cellulose (found in legumes, seeds, root vegetables, and vegetables in the cabbage family), wheat bran, and corn bran are examples of insoluble fiber.

High fiber substances containing both soluble and insoluble fibers have the properties of both. They include oat bran, psyllium, and soy fiber. Methylcellulose is a semi-synthetic fiber. It is soluble and gel forming, but not fermentable.

Types of fiber differ in the speed and extent to which they are digested in the GI tract, and in the process of fermentation. There may be both good and bad aspects to fermentation, but there are certainly metabolic products produced by fermentation which contribute to colonic health. The solubility and fermentation of a particular fiber affects how it is handled in the GI tract.

The effect of identical fibers varies from person to person. Individual response may vary and we encourage individuals try different types of fiber.

**Once a diagnosis of IBS is made, your physician may suggest the fibers listed below for treatment of various symptoms.**

IBS Symptoms	Fiber Treatment
Lower abdominal pain	Methylcellulose/Psyllium
Upper abdominal pain	Oatmeal/Oat bran/Psyllium
Constipation	Methylcellulose/Psyllium
Incomplete evacuation	Methylcellulose/Psyllium
Diarrhea	Psyllium/Oligofructose
Excessive gas	Methylcellulose/Polycarbophil

Nutrition therapy, with an emphasis on dietary fiber modification, appears to be a safe and effective initial treatment of gastrointestinal disorders, particularly in constipation prone individuals. Fiber intake can be tailored to the symptoms most evident and can be fine-tuned in partnership with a medical care provider.





## Tips for Adding Fiber to Your Diet

Making small, gradual changes can add up to a big difference in the nutritional value of your diet. Experiment with fresh foods and don't be afraid to try new foods and recipes. Here are a few practical tips for adding fiber to your diet.

### Vegetables

- Cook in microwave to save time and nutrients
- Cook only until tender-crisp to retain taste and nutrients

### Beans

- Replace the meat in salads and main dishes with presoaked dried beans and peas
- Presoaking reduces the gas-producing potential of beans if you discard the soaking water and cook using fresh water
- Use a slow cooker for bean soups and stews

### Fruit

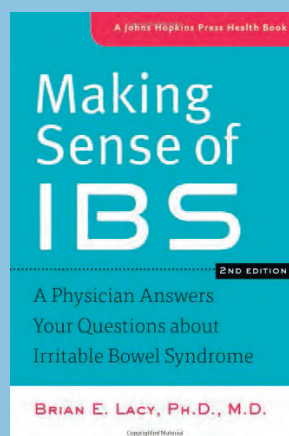
- Snack on fruit anytime, anywhere
- Experiment with unusual fruits such as kiwi, pineapple, and mangos
- Leave peelings on fruit whenever possible
- Use fresh and dried fruit in muffins, pancakes, quick breads, and on top of frozen yogurt

### Grains

- Choose whole-grain varieties of breads, muffins, bagels, and English muffins
- Try fresh pasta instead of dried
- Mix barely cooked vegetables with pasta for a quick pasta salad

Adapted from IFFGD publication 152, *Fiber Therapy in IBS and other GI Disorders*, by James W. Anderson, M.D.

## NEW BOOK OF INTEREST



***Making Sense of IBS: A Physician Answers Your Questions about Irritable Bowel Syndrome***

**Author:** Brian E. Lacy, Ph.D., M.D.

**Publisher:** 2nd Edition, Baltimore, Johns Hopkins University Press, 2013.

IBS, which affects almost one in six Americans, is characterized by abdominal pain, bloating, gas, and diarrhea or constipation. Today more than ever before, physicians are able to diagnose this complex disorder, understand and explain its origins, and develop a treatment plan that effectively meets the individual needs of a patient.

Drawing on his many years of experience treating people who have symptoms of IBS, Brian E. Lacy, M.D. explains normal digestion, the causes of IBS, how IBS is diagnosed, and what to expect with treatment. He also explores special topics such as IBS in children and psychological, hypnotherapeutic, and psychiatric therapies.

Important new information in the second edition includes: the roles of fiber, gluten, lactose, and fructose in the development and treatment of IBS; the use of probiotics and antibiotics to treat IBS; similarities and differences between IBS and inflammatory bowel disease (IBD); the relationship between small intestine bacterial overgrowth and IBS; how to make the most of your visits to a gastroenterologist; and lifestyle modifications that can improve symptoms of IBS.

This book is a resource for anyone who has symptoms or a diagnosis of IBS, as well as for health professionals who treat people with this complex disorder.

Available at [Amazon.com](http://Amazon.com)

## Clinical Corner

If you or a family member is struggling with chronic or recurring GI symptoms, you probably know how challenging it can be to find reliable treatment information. Clinical Corner provides answers from digestive health professionals to commonly asked questions and commentary on current issues in the GI field.

### IBS is No Joking Matter for Veterans and Others Living with this Condition



By: Douglas A. Drossman, M.D.

The new memoir by former Secretary of Defense Robert Gates is unexpectedly drawing attention to irritable bowel syndrome (IBS) after media reports highlighted a “special interest” request Gates received from Senator Harry Reid urging him to have the Defense Department invest in research into irritable bowel syndrome.

“With two ongoing wars and all [of] our budget and other issues, I didn’t know whether to laugh or cry,” Gates said in his book.

And in a January 16 NPR article titled *Doctors Say Reid’s Request for Bowel Research Money Is No Joke*, the writer, Susan Walsh, admitted that this request “drew snickers – and media attention, including here at NPR.”

As a physician who has worked with hundreds of people who are struggling to manage the often painful, debilitating and life altering symptoms of this common digestive condition, I can tell you IBS is no joking matter.

IBS is a chronic functional gastrointestinal disorder. For many sufferers it is marked by abdominal discomfort, bloating, constipation and/or diarrhea. It can also be categorized based on these symptoms: IBS-D is accompanied by diarrhea, IBS-C is accompanied by constipation, and IBS-M includes both diarrhea and constipation. Research suggests that IBS is caused by changes in the nerves and muscles that control sensation and motility of the bowel.

IBS affects 10 to 15 percent of the U.S. population and is 1.5 times more common in women than in men, according to the National Digestive Diseases Information Clearinghouse.

In 2010, I had the honor of serving on an Institute of Medicine committee that found that, in addition to Post-Traumatic Stress Syndrome, “a large number of veterans” of the 1991 Persian Gulf War were reporting long-term, multi-symptom health issues. These health issues included IBS, substance abuse, anxiety, and depression.

The report, “Health Effects of Serving in the Gulf War,” showed a relationship between military deployment and gastrointestinal infections, and also, post-infectious IBS. Although this study focused on the Gulf War veterans, subsequent studies of more recent returning veterans suggest that IBS and other health issues continue to impact our veterans.

I was pleased when NPR contacted me for comment on this article because it gave me an opportunity to shed some light on the seriousness of IBS, especially among the veteran population where post-infectious IBS is a common after-effect faced by our military upon return from active duty.

For a link to the full NPR article, as well as Dr. Drossman’s complete post, please visit [www.drossmancenter.com/ibs-joking-matter-veterans-others-living-condition](http://www.drossmancenter.com/ibs-joking-matter-veterans-others-living-condition).

Dr. Drossman currently sees patients at his practice, Drossman Gastroenterology, in Chapel Hill, North Carolina. You can learn more about his practice at [www.drossmangastroenterology.com](http://www.drossmangastroenterology.com).



**W**hen IFFGD began in 1991 there was little communication between patients living with functional GI and motility disorders and the companies with the means to develop treatment products and services. Subsequently, IFFGD has worked hard to make the needs of our members known – not only to the clinicians who see patients, but also to the researchers and providers of diagnostic and treatment methods and tools.

In an effort to strengthen our voice, in 1998 we formed the IFFGD Industry Council. The Council provides a forum to help ensure that the voice of our membership is heard.

We invite participation from companies with a demonstrated interest in these disorders. While we are grateful to our Industry Council members for their support, we do not endorse any specific product or company. IFFGD retains unrestricted control over the planning, content, objectives, methods, and execution of all initiatives and projects.

## IFFGD INDUSTRY COUNCIL

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## Industry Treatment News

### Data Supports Long-Term Use of Gattex for Treatment of Short Bowel Syndrome

Data from a two-year study by NPS Pharmaceuticals supports the long-term use of Gattex for injection in adult patients with short bowel syndrome (SBS). The findings were published as an abstract and presented at the American College of Gastroenterology (ACG) Annual Scientific Meeting and Postgraduate Course in San Diego, CA in October 2013. Patients in the study using Gattex beyond one year continued to be able to reduce their support on parenteral nutrition.

The open-label extension study included 88 adult patients with SBS. Investigators reported that the long-term use of Gattex in patients with SBS resulted in additional, clinically meaningful reductions in the volume and days per week of parenteral support requirements in this extension study. Thirteen patients in the study achieved complete independence from parenteral support with long-term Gattex therapy. No new unexpected safety concerns were observed with long-term Gattex treatment and the product's safety profile remains consistent with the product's label.

The drug works by regeneration of cells in the intestinal lining, slowing down transit through the gut and increasing blood flow, allowing for increased nutrient absorption. In studies, the drug was associated with achieving and maintaining clinically meaningful reductions in parenteral nutrition (PN) and intravenous (IV) fluid volume in adult subjects with SBS.

Gattex was approved by the U.S. Food and Drug Administration (FDA) in 2012 for treatment of adult patients with SBS who are dependent on parenteral support. To help ensure that the benefits of Gattex outweigh the risks for causing other serious conditions, the drug is approved with a Risk Evaluation and Mitigation Strategy, which patients need to discuss with their doctors. While the researchers found the safety profile to be acceptable, they advise that physicians closely monitor patients beginning the drug for side effects and possible need to adjust dosage.

SBS is a rare condition related to poor absorption of nutrients. It typically occurs in people who have a significant portion of their small intestine removed due to disease or injury. They cannot absorb enough water, vitamins, and other nutrients from food and may then need to use parenteral nutrition and intravenous fluids.

### Seeking Participants for Study to Assess Teduglutide as Treatment for Pediatric Short Bowel Syndrome

**Purpose of study:** This 12-Week, open label study will evaluate the effectiveness and safety of teduglutide as a treatment for pediatric patients with short bowel syndrome on parenteral support.

**Sponsored by:** NPS Pharmaceuticals, Inc

**Participation:** Eligible male and female patients aged 1-17 years.

**Contacts:** Clinical Operations,  
908-450-5300, [info@npsp.com](mailto:info@npsp.com); Be sure to refer to this study by its ClinicalTrials.gov identifier: NCT01952080





## Rifaximin Studied for Treatment of Non-Constipation IBS

Rifaximin is an antibiotic currently under investigation for the treatment of non-constipation IBS (Non-C IBS) and IBS-related bloating. Rifaximin works by reducing or altering bacteria in the gut. In studies it has been found to improve IBS symptoms of bloating, belly pain, and diarrhea after a 10–14 day course of treatment. It is only slightly absorbed in the gut and is generally tolerated well. Rifaximin has not yet been approved by the U.S. Food and Drug Administration (FDA) for the treatment of IBS.

### Seeking Participants for Study to Assess Repeat Treatment Efficacy and Safety of Rifaximin 550 mg TID in Subjects with Irritable Bowel Syndrome with Diarrhea (IBS-D)

**Purpose of study:** This study will evaluate the effectiveness and safety to repeat treatment with rifaximin 550 mg three times a day in patients with IBS with diarrhea who respond to initial treatment of rifaximin 550 mg three times a day.

**Sponsored by:** Salix Pharmaceuticals, Inc.

**Participation:** Eligible male and female patients aged 18 years and older with a diagnosis of irritable bowel syndrome (IBS) with a subtype of diarrhea.

**Contacts:** Rachel Ballard; [rachel.ballard@salix.com](mailto:rachel.ballard@salix.com) or Alyson Lineberry; [alyson.lineberry@salix.com](mailto:alyson.lineberry@salix.com)  
Be sure to refer to this study by its ClinicalTrials.gov identifier: NCT01543178

## Elobixibat for Treatment of Chronic Constipation Now in Phase 3 Clinical Trials

Phase 3 trials of elobixibat for the indication of chronic idiopathic constipation (CIC) have begun. Ferring Pharmaceuticals reports that two studies are being conducted at close to 200 sites around the world. In Phase 2b clinical trials in the U.S. and Europe, elobixibat (formerly A3309) demonstrated clinically meaningful, statistically significant, and dose-dependent improvements, including increased stool frequency and improved constipation-related symptoms such as straining, stool consistency, and bloating maintained over eight weeks of treatment.

Elobixibat is a first-in-class compound under investigation for treatment of CIC and for IBS with constipation (IBS-C). It works by reducing bile acid absorption in the small intestine. This stimulates bowel movements by increasing fluid secretions and motility in the colon.

### Participants Sought for Two Double-blind, Randomized, Placebo-controlled, Phase 3 Trials in Patients with Chronic Idiopathic Constipation to Demonstrate the Efficacy and Safety of Elobixibat 5 mg and 10 mg

**Purpose of study 1:** 26-week efficacy and safety trial for patients with chronic idiopathic constipation

**Sponsored by:** Ferring Pharmaceuticals

**Participation:** Eligible male and female patients aged 18 years or older

**Contacts:** Clinical Development Support, [DK0-Disclosure@ferring.com](mailto:DK0-Disclosure@ferring.com)

**Purpose of study 2:** 12-week Efficacy and Safety Trial Followed by a 4-week Withdrawal Period for Patients with Chronic Idiopathic Constipation

**Sponsored by:** Ferring Pharmaceuticals

**Participation:** Eligible male and female patients aged 18 years or older

**Contacts:** Clinical Development Support, [DK0-Disclosure@ferring.com](mailto:DK0-Disclosure@ferring.com)

## Solesta Available in the U.S. to Treat Bowel Incontinence

Solesta, a biocompatible tissue bulking agent, was approved by the U.S. Food and Drug Administration (FDA) for the treatment of bowel incontinence in patients 18 years and older who have failed conservative therapy (e.g., diet, fiber therapy, anti-motility medications). The drug has been approved to treat bowel incontinence in the U.S. since 2011 and in Europe since 2006. Bowel incontinence is the involuntary loss of bowel control. While the exact mechanism of action has not been identified, it is thought that the Solesta injections may narrow the anal canal and allow for better control of those muscles.

Solesta is an injectable gel delivered into the anal canal in an outpatient procedure taking approximately 10 minutes without the need for surgery or anesthesia. It should only be administered by physicians who are experienced in performing anorectal procedures and have successfully completed a comprehensive training and certification program in the Solesta injection procedure. It should *not* be used in patients who have active inflammatory bowel disease, immunodeficiency disorders, previous radiation treatment to the pelvic area, significant rectal prolapse, active infections, bleeding, tumors or malformations in the anorectal area, rectal distended veins, an existing implant in the anorectal region, or allergy to hyaluronic acid based products.

The most common side effects associated with Solesta include injection area pain and bleeding. Infection and inflammation of anal tissue are more serious risks, but are less common.

Solesta is a registered trademark of Q-Med AB of Uppsala, Sweden; Oceana Therapeutics acquired exclusive worldwide sales and distribution rights to Solesta in June 2009. In December 2011 Salix Pharmaceuticals, Ltd. acquired all of the outstanding stock of Oceana Therapeutics, Inc.



### **Linacotide (Constella) Available in Europe for Treatment of IBS-C**

Linacotide is the first medicine approved by the European Commission for the symptomatic treatment of moderate to severe irritable bowel syndrome with constipation (IBS-C) in adult patients. It is currently available in several European countries with the EU brand name Constella.

Linacotide, a guanylate cyclase type-C (GC-C) agonist, is a prescription drug used to relieve symptoms of abdominal pain, discomfort, bloating, and bowel symptoms in people who have IBS-C or chronic constipation (CC). It has been shown to be safe and effective in trials. It works by increasing the amount of fluid that flows into the bowel, allowing stool to pass more easily, and reducing visceral pain.

Linacotide (Linzess) has been available in the U.S. to treat IBS-C and CC in adults aged 18 and older since 2012. Linzess should *not* be used in patients 17 years of age or younger. Linzess should *not* be used in patients with known or suspected mechanical gastrointestinal obstruction. The most common side effect reported during clinical studies was diarrhea.

Linacotide is being co-produced in the U.S. by Ironwood and Forest. Ironwood has out-licensed linacotide to Almirall, S.A. for development in Europe; and to Astellas Pharma, Inc. for development in Japan, Indonesia, Korea, the Philippines, Taiwan, and Thailand.

### **Lubiprostone is Approved by the FDA to Treat Opioid-Induced Constipation**

Sucampo Pharmaceuticals, Inc. and Takeda Pharmaceuticals U.S.A. Inc. announced earlier this year that the U.S. Food and Drug Administration (FDA) approved the supplemental New Drug Application for lubiprostone (Amitiza) to treat opioid-induced constipation in adult patients with chronic non-cancer pain. The drug was approved to treat chronic idiopathic constipation (CIC) in adults in 2006 and to treat IBS with constipation (IBS-C) in adult women in 2008.

Amitiza is a prescription drug used to relieve abdominal pain, bloating, and straining and produce softer and more

frequent bowel movements in men and women who have CIC. It is also used to treat IBS-C in women who are at least 18 years of age. Amitiza works by increasing the amount of fluid that flows into the bowel and allowing the stool to pass more easily.

The drug met the primary endpoint in a Phase 3 clinical trial for the treatment of opioid-induced bowel dysfunction in patients with chronic, non-cancer pain, excluding those taking methadone. Opioids are narcotics (such as morphine and codeine) used to treat pain. A number of gastrointestinal (GI) symptoms are potential side effects of using opioid-based medications. The most common symptom is constipation. Other symptoms may include decreased gastric emptying, abdominal cramping, spasm, bloating, and delayed-GI transit.

### **Clinical Trial of Lubiprostone Liquid Formulation for Treatment of Chronic Constipation**

The makers of lubiprostone (Amitiza) have announced a randomized, placebo-controlled, double-blinded, multi-center study of a liquid form of lubiprostone in adult subjects with chronic idiopathic constipation (CIC). The trial is expected to enroll 152 patients with CIC at approximately 11 sites in the U.S. A liquid formulation could possibly offer an alternative dosing option for a wider range of patients.

### **Swiss Prescribing Regulations for Amitiza Relaxed**

In early February 2014 it was reported that the Swiss Federal Office of Public Health has lifted several limitations on prescribing Amitiza (lubiprostone) to patients with chronic idiopathic constipation (CIC). The changes make Amitiza more widely available to patients. Patients can now be prescribed Amitiza from all physicians, not just gastroenterologists, and can be using the prescription for up to a year before a prescription review is required.

## **Medical and Research News**

### **Hospitalizations for Constipation Increasing in Cost and Frequency**

New data shows that hospitalizations for constipation are increasing in frequency, and the associated costs are rising. Researchers analyzed the National Inpatient Sample Database for hospital discharge codes related to constipation, from 1997-2010. This database contains records for over 7 million hospital visits per year.

From 1997 to 2010, discharges with a principal diagnosis of constipation increased by 128.6%. The average hospital charges for these patients increased 239.3% (\$8,869 in 1997, adjusted for inflation, to \$17,518 in 2010), although the average length of hospital stay only increased from 3.0 to 3.1 days in the same time.

The researchers speculate that the increase in hospitalizations for constipation may be due to the increasing use of medications that cause constipation, and that the cost increase is likely due to the increased number of diagnostic tests performed to test colon function. They conclude that constipation is an escalating burden on the health care system and recommend studies on preventative measures that could reduce this.

### **New Treatment for IBS with Diarrhea Available for Men in Japan**

Ramosetron hydrochloride (HCl) tablets have been approved in Japan for treating IBS-D in males. The drug will be available under the brand name Irribow OD.

Ramosetron HCl is a serotonin 5-HT<sub>3</sub> receptor antagonist. It acts on 5-HT<sub>3</sub> receptors in the gut to slow intestinal transit and can also reduce transmission of intestinal pain. It is currently only approved for use in select countries including Japan and India, but is under investigation in several other countries.

### Positive Phase 3 Trial Results of Eluxadoline in Patients with IBS-D

Two Phase 3 clinical trials evaluating eluxadoline in the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D) have shown that the medication helps improve both stool consistency and abdominal pain.

The manufacturer, Furiex Pharmaceuticals, is hoping to file a New Drug Application with the FDA sometime in mid 2014. Eluxadoline has been granted Fast Track status by the FDA, a process designed to facilitate development and expedite the review of drugs to treat diseases with significant unmet medical need.

### Study Reports on Metaclopramide Nasal Spray Treatment for Gastroparesis

A Phase 2b study of a new method for treating nausea and vomiting in diabetic gastroparesis seems to show benefit over a traditional form of the treatment.

The study looked at the efficacy and safety of metoclopramide as taken by a new nasal-spray delivery method versus by the usual oral tablets.

Delayed gastric emptying symptoms, which are typical of gastroparesis, can interfere with the absorption and efficacy of oral medications. A nasal spray is absorbed through the nasal membrane bypassing the gastric emptying. A Phase 3 study to further investigate the potential of this form of treatment is upcoming.

### Probiotic Treatment for IBS Available Over the Counter in Ireland

An over the counter probiotic treatment for IBS is now available in Ireland. The active probiotic culture, *Bifidobacterium infantis* 35624, was originally discovered at the University College Cork, Ireland in the late 1990s. Since then, it has undergone clinical trials which have validated its efficacy in treating IBS symptoms. This probiotic has already been approved for over the counter use in the US and Canada under the brand name Align, and will be sold under the brand name Alflorex in Ireland.

### New Type of Fiber to be Tested in Treating IBS Symptoms

Scientists from two universities are collaborating to develop and test a new type of fiber that may be useful in treating IBS.

The fiber was designed to reduce bloating, a common side effect of current fiber therapies for IBS. It was also designed to break down into a product which helps promote healthy intestinal flora, and to deliver these nutrients farther into the large intestine. Most fibers are broken down in the stomach and small intestine.

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) has awarded these researchers a grant to conduct a two-year clinical trial which will test the new fiber. The trial will be starting in early 2014.

### FDA Offers New Online Reporting Method for Dietary Supplements

U.S. Food and Drug Administration (FDA) is now accepting online submission of adverse event reports related to the use of dietary supplements. Both mandatory and voluntary adverse event reports may be submitted online.

Reporting of dietary supplement adverse events is important in protecting consumers' health and safety. The FDA routinely monitors the marketplace. However, with more than 85,000 dietary supplements on the market and no product specific registration requirement, adverse event reporting is invaluable in identifying harmful products.

To submit a dietary supplement adverse event report, visit [www.safetyreporting.hhs.gov](http://www.safetyreporting.hhs.gov).

### Social Security Announces New Compassionate Allowances Conditions

The Social Security Administration (SSA) announced early this year that they have added 25 new Compassionate Allowances conditions, including chronic intestinal pseudo-obstruction (CIP).

CIP is a rare disorder of gastrointestinal motility where coordinated contractions (peristalsis) in the intestinal tract become altered and inefficient. When this happens, nutritional requirements cannot be adequately met. Pseudo-obstruction in children is usually congenital, or present at birth. It may also be acquired, such as after an illness. Read more about the symptoms and treatment of CIP at this IFFGD web page: [www.aboutkidsgi.org/site/about-gi-health-in-kids/functional-gi-and-motility-disorders/intestinal-pseudo-obstruction](http://www.aboutkidsgi.org/site/about-gi-health-in-kids/functional-gi-and-motility-disorders/intestinal-pseudo-obstruction).

The Compassionate Allowances program expedites disability decisions for Americans with the most serious disabilities to ensure that they receive their benefit decisions within days instead of months or years. Read the full press release at [www.ssa.gov/pressoffice/pr/compassionate-allowances-0114-pr.html](http://www.ssa.gov/pressoffice/pr/compassionate-allowances-0114-pr.html).

### Ondansetron May Ease IBS-D Symptoms

A new study from Garsed and colleagues in the UK suggests that the prescription drug ondansetron (Zofran, Zuplenz) may relieve some of the symptoms of diarrhea-predominant IBS (IBS-D). Ondansetron has been in use for many years to decrease nausea and vomiting related to chemotherapy.

In the study, ondansetron was most useful to improve frequent loose stools and urgency in people with mild to moderate symptoms. No significant improvement was seen in abdominal pain. Reportedly, any benefit is usually seen within a few days.

The study was published in the journal *Gut* in December and is available online at [www.gut.bmj.com/content/early/2013/12/12/gutjnl-2013-305989.abstract](http://www.gut.bmj.com/content/early/2013/12/12/gutjnl-2013-305989.abstract).





## Comprehensive Nonsurgical Treatment Helps Women with Pelvic Floor Dysfunction

Many women suffer from pelvic floor dysfunction (PFD), which can cause a range of symptoms that include bladder and bowel problems, such as constipation or incontinence, as well as pelvic pain.

A retrospective study from the University of Missouri concluded comprehensive pelvic floor rehabilitation, which may include exercises to strengthen or relax the pelvic muscles, biofeedback therapy, constipation management, medications, incontinence devices, and behavioral modification, can help provide relief without surgery.

Existing records from nearly 800 women who had undergone therapy were examined. Those who completed at least five comprehensive rehabilitation sessions reported an average of 80% improvement in urinary incontinence, bowel dysfunction, and pelvic pain. Women who have symptoms of pelvic floor dysfunction are encouraged to discuss their concerns and treatment options with their health care providers.

## New Use for Imaging Technique in Treatment of IBS

Researchers at the University of Nottingham, including IFFGD Advisory Board member Robin Spiller, M.D., are studying how Magnetic Resonance Imaging (MRI) can be used to study IBS.

In three new studies, Dr. Spiller and colleagues have used MRIs to study the volume of the colon and how it expands to make space for a meal; the transit time of a meal through the bowel; and how certain food triggers such as fructans and glucose act differently in different parts of the colon.

Their findings will help show how the bowel functions differently between healthy individuals and those with IBS. “In future,” says Dr. Spiller, “We will be able to use our MRI techniques to test specific foods to understand how they will affect IBS.”

## FDA Issues Warning to Consumers on Certain OTC Laxatives

The Food and Drug Administration (FDA) recently issued a warning to consumers that some of the over-the-counter (OTC) laxatives – those called sodium phosphate laxatives – are potentially dangerous if dosing instructions or warnings on the Drug Facts label are not properly followed or when there are certain coexisting health conditions.

The label of sodium phosphate laxatives states that they should be used as one dose per day for no more than three days. If you do not have a bowel movement after taking a dose, you should not take another dose of the product.

FDA is now warning that adults older than 55, and adults and children with certain health conditions or who are using certain other medications – including ibuprofen – should ask their doctor before using these products because they may be at increased risk for harmful side effects. These new warnings are not currently in the Drug Facts label and apply to both adults and children. Read the full FDA update at [www.fda.gov/ForConsumers/ConsumerUpdates/ucm379440.htm](http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm379440.htm).

## NIDDK Staff Contributes to Revision of Dietary Guidelines for Americans

Starting this year, researchers and federal staff with diverse expertise, including many with ties to the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), have embarked on an endeavor aimed at improving nutrition for all: Updating the Dietary Guidelines for Americans for 2015.

“The Guidelines provide practical, science-based advice to help Americans make food and physical activity choices that promote good health, a healthy weight and disease prevention for those ages 2 years and older,” said Dr. Van S. Hubbard, director of the NIH Division of Nutrition Research Coordination (DNRC), housed within NIDDK.

More information, including federal dietary guidance and nutrition education resources for children and adults are listed at <http://dnrc.nib.gov/education.asp>.

## NIDDK Unveils Improved Website

After two years of planning, the NIDDK has unveiled an improved website. The new site makes it easier to find grant and research programs, while keeping focus on their easy-to-use health education and education pages. Visit the new site at [www.niddk.nih.gov](http://www.niddk.nih.gov).

## “FODMAP Friendly” Food Certification Now Available in Australia

Food products that are low in FODMAPs (which stands for Fermentable Oligosaccharides, Disaccharides, Monosaccharides and Polyols) can now display a certification that identifies them as such in Australia.

The FODMAP Friendly logo was developed by Advanced Accredited Practicing Dietitian Dr. Sue Shepherd and is the first Australian Government-approved labeling system for fructose-friendly and lactose-friendly foods.

FODMAPs are a collection of sugars and related molecules that are found naturally in foods, and can often trigger symptoms of irritable bowel syndrome (IBS). Read more about FODMAPs at [www.aboutibs.org/site/treatment/low-fodmap-diet/](http://www.aboutibs.org/site/treatment/low-fodmap-diet/).

## IBS Patients’ Self-Health Ratings Look Beyond GI Symptom Severity

People with IBS tend to base self-ratings of health by including other factors in addition to their IBS symptoms, a recent study suggests. The study looked at a sample of people with moderate to severe IBS, in order to understand how they rate their own health. The resulting self-ratings were correlated more with physical, psychological, and social issues rather than just with their IBS symptom severity. Worse perceptions of health included more severe non-digestive symptoms (such as fatigue), greater psychological distress, and more stressful life circumstances. This finding suggests that improving treatments for IBS requires addressing more than just IBS symptom severity in order to increase an individual’s overall perception of health.



## Upcoming Events and Meetings

Here are some events coming up that may be of interest to the digestive health community.

### **Society of American Gastrointestinal and Endoscopic Surgeons 2014 Annual Meeting**

**When:** April 2–5, 2014

**Where:** Salt Lake City, UT

**Website:** [www.sages2014.org](http://www.sages2014.org)

### **Society of Gastroenterology Nurses and Associates 41st Annual Course**

**When:** May 2–6, 2014

**Where:** Nashville, TN

**Website:** [www.sгна.org](http://www.sгна.org)

### **Digestive Disease Week 2014**

**When:** May 4–6, 2014

**Where:** Chicago, IL

**Website:** [www.ddw.org](http://www.ddw.org)

Visit IFFGD at Booth #2911!

### **American Society of Colon and Rectal Surgeons Annual Scientific Meeting**

**When:** May 17–21, 2014

**Where:** Hollywood, FL

**Website:** [www.fascrs.org](http://www.fascrs.org)

### **DHA Advocacy Call-in Day**

**When:** June 17, 2014

**Where:** All across America

**Website:** [www.DHA.org/advocacy2014-call](http://www.DHA.org/advocacy2014-call)

### **Treatment of Bowel, Bladder, and Pelvic Floor Disorders**

**When:** June 18–21, 2014

**Where:** Milwaukee, WI

**Website:** [www.marquette.edu](http://www.marquette.edu)

### **DHA Advocacy Day**

**When:** June 23–24, 2014

**Where:** Washington, D.C.

**Website:** [www.dha.org/advocacy2014](http://www.dha.org/advocacy2014)

### **American Neurogastroenterology and Motility Society Clinical Practice**

**When:** July 24–27, 2014

**Where:** Baltimore, MD

**Website:** [www.motilitysociety.org](http://www.motilitysociety.org)

### **Federation of Neurogastroenterology and Motility (FNM, previously NGM)**

**When:** September 5–7, 2014

**Where:** Bangkok, Thailand

**Website:** [www.fnm2014.org](http://www.fnm2014.org)

### **Behavioral and Rehabilitation Treatment of Bowel Disorders – An Advanced Course**

**When:** October 16–18, 2014

**Where:** Milwaukee, WI

**Website:** [www.marquette.edu](http://www.marquette.edu)

### **2014 ACG Annual Scientific Meeting and Post Graduate Course**

**When:** October 17–22, 2014

**Where:** Philadelphia, PA

**Website:** [www.gi.org](http://www.gi.org)

### **2014 NASPGHAN Annual Meeting and Post Graduate Course**

**When:** October 23 – 26, 2014

**Where:** Atlanta, GA

**Website:** [www.naspgban.org](http://www.naspgban.org)



## Progress in Washington, D.C. for Pediatric Health

On November 27, 2013, President Obama signed the *National Pediatric Research Network Act* into law as a part of a larger package of health-related bills. The law authorizes the National Institutes of Health (NIH) to carry out the Pediatric Research Initiative and to act through the Director of the National Institute of Child Health and Human Development (NICHD) to create a **National Pediatric Research Network**.

Support for the National Pediatric Research Network has been a part of the IFFGD/DHA Legislative Agenda for years, so we are excited to see this critical health bill finally become law. Key provisions of the *National Pediatric Research Network Act* include:

- The creation of pediatric research consortia, with each consortium containing multiple participating institutions.
- The selection of consortia through a competitive peer-review process.
- Support for the pediatric research consortia for up to five years, which may be extended at the discretion of the Director of NIH.
- A focus on pediatric rare diseases or genetic conditions.



“This legislation is critical for advancing children’s health,” said Senator Sherrod Brown of Ohio, a strong supporter of this bill. “It will strengthen the federal investment in pediatric research by ensuring adequate funding for infrastructure and core services needed to support pediatric basic, translational and clinical research, and it will help accelerate basic research in fields that show special promise,” Brown said.

In 2009 IFFGD recognized Senator Brown with our Congressional Champion Award for his work on behalf of the digestive disease community.

The *National Pediatric Research Network Act* will help medical researchers, potentially including those involved in the DHA Children’s GI Research Network, collaborate to better serve pediatric patients with chronic GI conditions.

### The DHA Children’s GI Research Network:

- Carlo Di Lorenzo, M.D., Nationwide Children’s Hospital, Columbus, OH
- Paul Hyman, M.D., Children’s Hospital, Louisiana State University, New Orleans, LA
- Jeffrey Hyams, M.D., Connecticut Children’s Hospital, Hartford, CT
- Manu Sood, M.D., Children’s Hospital of Wisconsin, Milwaukee, WI
- Miguel Saps, M.D., Children’s Memorial Hospital, Chicago, IL
- Samuel Nurko, M.D., M.P.H., Children’s Hospital Boston, Boston, MA
- Marc Benninga, M.D., Emma Children’s Hospital, Amsterdam, The Netherlands

## Funding Levels for NIH, FDA, and Gulf War Illness Research Set for FY14

The *Consolidated Appropriations Act, 2014* was signed into law by President Obama on January 17, 2014. It details how the federal government will spend its money for fiscal year (FY) 2014.

The overall FY 2014 federal spending level is set at \$1.012 trillion. The *Consolidated Appropriations Act, 2014* includes funding levels for the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and the Gulf War Illness Research Program – all areas of interest for IFFGD/DHA and other members of the digestive health community.

### Key Health-Related Funding Provisions

- Funding for NIH at a level of \$29.9 billion, \$1 billion above FY 2013 levels.
- Funding for FDA at a level of \$2.552 billion, an increase of \$91 million above FY 2013.
- Restoration of \$85 million in FDA user fees, which were sequestered in FY 2013. These fees help fund programs like PDUFA and the patient-focused drug development initiative.
- Funding for the Gulf War Illness Research Program at a level of \$20 million, the same funding level as FY 2013.

## Be an Advocate for Digestive Health

You are invited to participate in the 7th annual **DHA Advocacy Day** in Washington, D.C. on **June 23-24, 2014**! DHA, the Digestive Health Alliance, is the grassroots arm of IFFGD.

You can help fill the information gap surrounding functional GI and motility disorders in Washington, D.C. by becoming an advocate for digestive health. Your outreach to Members of Congress will help educate policymakers about the needs of patients and inform them of how they can take meaningful action.

Through participating, you will take part in the legislative process by sharing your story with your Members of Congress. Without your voice, your legislators will not hear and understand the importance of these critical issues.

We hope to see you in Washington D.C. for DHA Advocacy Day 2014. Together we can make a difference!

### Event Details

DHA Advocacy Day 2014 will start Monday afternoon at the Phoenix Park Hotel with registration, legislative updates, and dinner. We will meet at the Phoenix Park Hotel again Tuesday morning for breakfast and advocacy training, before walking a few blocks to Capitol Hill. The event should wrap up on Capitol Hill by 4:30pm.

If you plan to attend, please register by **Friday, May 30th**. You can register online at [www.dba.org/advocacy2014](http://www.dba.org/advocacy2014) or by phone at (414) 964-1799.

There is no fee to participate in Advocacy Day; however participants are responsible for their own transportation and lodging expenses. Dinner will be provided on Monday, June 23rd; breakfast and lunch will be provided on Tuesday, June 24th.

### Hotel Information

A block of rooms has been set aside at The Phoenix Park Hotel on Capitol Hill at a special rate of \$244 a night (plus tax) for DHA Advocates.

#### Phoenix Park Hotel

520 North Capitol Street, N.W.  
Washington, D.C. 20001

If you are interested in staying at the Phoenix Park Hotel, please contact them directly to make your reservation:

- Book online at <http://www.dba.org/advocacy2014/hotel>
- Or call 800-824-5419 or 202-638-6900, and be sure to mention that you are attending the “**DHA Advocacy Day**” and mention “**Group Code 18529**.”

### Attendee Sponsorships Available

A limited number of attendee sponsorships are available to help offset some of the cost with attending this special event.

These sponsorships will cover lodging for Advocacy Day events, specifically one hotel room for up to three nights for the attendees of DHA Advocacy Day (including only the night before and/or the night(s) of DHA Advocacy Day). The sponsorships will cover only lodging for the attendee at the Phoenix Park Hotel, which will be arranged through DHA, and sponsored attendees are responsible for all other costs of attending Advocacy Day, including travel.

Learn more and apply at [www.dba.org/advocacy2014-sponsorship](http://www.dba.org/advocacy2014-sponsorship).

Please make sure you make your reservations with the Phoenix Park Hotel **before Monday, May 23rd** to receive the group rate.

Located next to downtown Washington's transportation hub, Union Station, the Phoenix Park Hotel is conveniently just two blocks from the U.S. Capitol Building. The hotel is also within walking distance of the famed National Mall where visitors can experience the Lincoln Memorial, the Washington Monument, and the Smithsonian Museums. Additional information about the hotel can be found at [www.phoenixparkhotel.com](http://www.phoenixparkhotel.com).

### Digestive Health Call-In Day



### Can't make it to Washington, D.C.? Advocate for digestive health from home!

Join the Digestive Health Alliance for the **Digestive Health Congressional Call-In Day on Tuesday, June 17th**. You can send an impactful message to your Member of Congress with one simple phone call.

You will receive more information about this important annual event later this spring, so watch your mailbox for more from IFFGD.

To find out more about the Digestive Health Congressional Call-In Day now, go to [www.DHA.org/advocacy2014-call](http://www.DHA.org/advocacy2014-call).

## Lonnie's Advocate in Action Story

Since founding the Cheryl Aaron Memorial Fund in March 2012 in honor of his wife, Lonnie has become super involved in advocating, raising awareness, and funding research for gastroparesis. So it only made sense that he would take part in the 2013 DHA Advocacy Day in Washington, D.C. Below is what Lonnie had to say about his first Advocacy Day:

I wasn't sure what to expect from my trip to Washington, D.C. This is the first time I've ever done anything like this. It was an opportunity to meet people that are advocates for functional gastrointestinal and motility disorders (FGIMDs) and to be an advocate myself.

It's amazing how much of an instant connection you feel meeting people who are fighting for the same cause. I met people that have been, in one way or another, directly affected by gastroparesis. One of my goals was to use this event to connect with others affected by this disease and start to build a network of new friends. Crystal Saltrelli is a gastroparesis diet & lifestyle counselor and has been living with gastroparesis. She wrote a book titled *Living (Well!) With Gastroparesis* (to learn more about Crystal and purchase her book go to [www.livingwithgastroparesis.com](http://www.livingwithgastroparesis.com)). I also met Malinda. I learned that she started running when she was 22. Over the last 18+ years, Malinda has run in dozens of races and completed eight marathons while living with gastroparesis. (To find out more about Malinda go to [www.twinsruninourfamily.com](http://www.twinsruninourfamily.com).)

We met with Senatorial and Congressional staff members from the state of Pennsylvania to urge them to champion FGIMD research. Our visits were with the Office of Senator Bob Casey, the Office of Senator Patrick Toomey, the Office of Representative Patrick Meehan, and the Office of Representative Tim Murphy.

Each meeting opened with a member of the Digestive Health Alliance's Washington representatives discussing the Digestive Health Alliance, the National Institutes of Health (NIH), *The Functional Gastrointestinal and Motility Disorders Research Enhancement Act* (H.R. 842), functional GI disorders and the military service connection, and *The National Pediatric Research Network Act* (H.R. 225/S. 424).

The meeting was then turned over to us for our personal stories. Each of us took several minutes to talk about our experiences. Each meeting closed with us asking for the representatives to become cosponsors of H.R. 842, to work to see that funding for the Gulf War Illness Research Program (GWIRP) is included in FY 2014 Defense Appropriations, work to ensure that H.R. 225/S. 424 is passed by the Senate and signed into law during the 113th Congress, and I was given the opportunity to discuss the Cheryl Aaron Memorial Fund.

I want to think we made a difference and the Senators and Congressmen will hear and act on our requests. We didn't get a chance to meet any of the representatives directly, which was disappointing but understandable. We discussed the possibility of Representative Murphy attending our July 9th awareness/fundraising event.

I can honestly say I was nervous and not very effective in the first two meetings. After the second meeting I had a little discussion with myself. This was the opportunity that I couldn't blow. I asked Cheryl to help me through the rest of the day. I felt a surge of calmness and confidence. The rest of the day went much, much better. In fact I didn't want to stop.

This was a tremendous experience and opportunity! I met a group of wonderful people that I hope to see again. This event will be on my calendar every year. I'm already excited about next year!





## IFFGD Presents Gastroparesis Research Grants With Help of Grassroots Fundraisers

In February 2014, IFFGD awarded three \$40,000 grants to support innovative research into idiopathic gastroparesis, a chronic digestive disease that affects adults and children.

The grants were made possible by donations to IFFGD, as well as money raised by fund raisers through our grassroots arm, the Digestive Health Alliance (DHA). We are very grateful to all of you who donated in support of this research, including:

- Major Contributor
  - o The Zebrowski Family Foundation
- Contributors
  - o The Cheryl Aaron Memorial Fund (CAMF) in Pittsburgh
  - o The Mary H. Storer Foundation
  - o The Annual Awareness Walks for Gastroparesis and Digestive Health in Bellingham, WA
  - o The Half Marathon for Gastroparesis in Pittsburgh, PA
  - o All of you who made individual donations

Applications for the IFFGD grants were submitted from around the globe. An independent selection committee of medical professionals reviewed the grant proposals. After careful consideration, applications from the following three investigators were chosen to receive the grants:

- Leo K. Cheng, Ph.D., Auckland Bioengineering Institute, The University of Auckland
- Braden Kuo, M.D., Massachusetts General Hospital
- Richard W. McCallum, M.D., Texas Tech University Health Sciences Center

Idiopathic gastroparesis is a chronic condition where the muscle contractions (motility) that move food along the digestive tract do not work properly and the stomach empties too slowly. There is no observable obstruction or blockage and the cause is unknown. Symptoms vary from person to person, but include nausea and vomiting after eating. Other symptoms may be feelings of fullness when eating, inability to finish a meal, as well as stomach discomfort or pain. The severity of the condition ranges from uncomfortable to debilitating, and can be life-threatening.

These IFFGD research grants will be used to explore new options for diagnosis and treatment of idiopathic gastroparesis.

**“Increased understanding of these conditions can only come from more research and advanced science. We are pleased to be able to give patients, families, and friends a way to contribute to this advancement and help broaden the understanding of the conditions that affect their lives day to day.”**

— Nancy J. Norton, IFFGD president and founder

In this era of federal budget constraints, funding for seed grants like these is becoming more difficult to come by. IFFGD supports research grants to help fill that gap. These grants promote interest and opportunity in the field of functional gastrointestinal and motility disorders, like gastroparesis, so that new treatment answers can begin to be found for those affected by the conditions.

For more information about gastroparesis, visit IFFGD's dedicated website, [www.aboutgastroparesis.org](http://www.aboutgastroparesis.org). If you are experiencing symptoms of the condition, see your health care provider. To learn more about how you can support research into conditions like gastroparesis, visit [www.aboutgastroparesis.org/support-research](http://www.aboutgastroparesis.org/support-research).



## Meet the Grant Recipients



**Braden Kuo, M.D.** is an Assistant Professor of Medicine at Harvard Medical School and Director of the GI Motility Laboratory in the GI Unit at Massachusetts General Hospital in Boston, MA.

His interest in GI motility has stemmed from his days as a medical student and has continued to this day. His work focuses on brain-gut interactions using functional magnetic resonance imaging (MRI) for gut sensations such as nausea, pain, and feeling of fullness (satiation) as well as work elucidating gut motility with the development of technologies to non-invasively measure gut transit and motility in health and diseases such as gastroparesis, functional dyspepsia and constipation.

With support of the IFFGD grant, Dr. Kuo's research will aim at using MRI as a non-invasive way to measure gut transit and motility as well as to better understand the biomechanical properties of the stomach wall and motor function in individuals.

The ultimate goal is to have one technique that doctors can use which tests for multiple abnormalities at the same time, and serves as a guide for diagnosis and individualized treatment in idiopathic gastroparesis.



**Richard W. McCallum, M.D.** is Professor and Founding Chairman of the Department of Internal Medicine, Paul L. Foster School of Medicine, Texas Tech University Health Sciences Center at El Paso. Dr. McCallum also serves as Chief of the Research Division of Gastroenterology, Hepatology and Nutrition and as the Medical Director of the Diagnostic Center for GI Motility and Functional Bowel Disorders, a referral center for patients locally, regionally, and nationally.

Dr. McCallum's research has focused on the physiology, pathophysiology, and pharmacology of gastrointestinal smooth muscle and the role of nerves and electrical activity relating to functional GI and motility disorders. His past research has resulted in several innovative approaches to diagnosing and treating these conditions.

With support of the IFFGD grant, Dr. McCallum's research will be aimed at defining the role of nerves and electrical activity in stomach motility and in the generation of symptoms in gastroparesis. Using non-invasive electrical stimulators, not needles, the research will explore the use of acupuncture points to reduce nausea and vomiting.

The ultimate goal is to provide a new and practical therapy option for the treatment of the symptoms and of their complications.



**Leo K. Cheng, M.D.** is currently an Associate Professor at Auckland Bioengineering Institute at the University of Auckland, New Zealand. He is also an Adjunct Research Assistant Professor at the Department of Surgery, Vanderbilt University, Nashville, TN.

His research uses a variety of bioengineering and mathematical modeling approaches to help provide novel insights into the mechanisms underlying gastrointestinal motility disorders. His research interests span from basic sciences to the development of new techniques and devices that can be applied clinically.

The IFFGD grant will be used to support Dr. Cheng's research aimed at developing a method that can identify the underlying signaling pattern that is controlling and coordinating a person's stomach motility.

The ultimate goal is to create a tool that doctors can use in clinical practice when treating individuals with idiopathic gastroparesis and chronic unexplained nausea and vomiting.



## Stories from the Community

At DHA.org members of the digestive health community are sharing their stories and experiences. They serve as a reminder that you aren't alone and that there are others out there who are facing the same struggles. Here are some of those stories:

### Lauren

As I sit here in my college classroom, grasping and rubbing my poor belly, I just want to cry. I have had IBS since I was in fifth grade. It has progressively gotten worse. I am now in my twenties and fear this painful quality of life will last forever. I wish I had helpful advice to give, but I am only full of suffering. I can't concentrate on school when I'm in pain. If I eat at school, I know I'll get painful cramps, but if I don't I can't eat for hours (8-3)! I feel stuck and desperate. The doctors are no help. It's like they don't care at all. If I was in any other kind of pain, they would give me something, but because it is IBS, I should "just deal with it." What a messed up concept! I hope I won't live like this forever...back to trying to pay attention to class...

Find Lauren's story online at [www.dba.org/Lauren-Story](http://www.dba.org/Lauren-Story).

### Amber

I am a 30 year old female. I've been living with IBS since I was 12. Let's just say some days feel so long when dealing with this problem. I remember as a teen waking up every night with stomach cramps. That's how it all started. High school was a nightmare having to map out the closest route to a restroom and my mother having to talk to the principal and teachers to let them know I have to be able to leave the room at any time. Missing too many school days. College wasn't much better. Had to suck up pain through exams and long classes. I'm sure many of you had the same experiences. A few years back my gallbladder decided to say it was through with me and I felt better for a year then all the IBS symptoms returned with a vengeance. The past two years have been horrible. Chronic gastritis and GERD to go along with the IBS. My gastro wasn't any help. Prescribed proton pump inhibitors which made things worse. My regular doc is going to let me try Librax. I have heard good things about this drug. I hope it helps. Good Luck everyone!

Find Amber's story online at [www.dba.org/Amber-Story](http://www.dba.org/Amber-Story).

### Steven

I'm a 26 year old male from Australia with mainly dyspeptic symptoms of bloating and tightness in the stomach/upper abdominal area. It started a few years ago when I had very large meals I would noticed I get bloated and feel constipated afterwards. I attributed it to just eating too much.

Since 2013 these symptoms came on more frequently and with just regular sized meals, primarily the bloating and a feeling of my stomach becoming really tight and heavy. In the past six months the feeling of tightness kind of just lingers around, even in the hours between meals. It's just a frustrating sensation to have to deal with constantly. It really puts me off going out with friends because I find it difficult to be "in the moment" when I'm consistently in discomfort. Nowadays I accept that is the case and I just go out when I'm not feeling so bad, and I don't feel guilty anymore for turning down events (well, much less so).

Interestingly, I always read stories about people with dyspepsia having reflux and gastric pain but I don't have any pain whatsoever (thank god), but the discomfort/tightness is terrible. Anyone else have symptoms like mine?

I've had the usual upper/lower endoscopies with no findings, so the doctors just labelled me with functional dyspepsia to explain the bloating/stomach discomfort and IBS to explain the constipation. I've taken some prokinetics (Motilium and Reglan) but they didn't seem to do much. Although I've read some very promising studies regarding a drug called acotiamide that helps with the symptoms I have. I really encourage you guys to check it out on google if you're in my boat!

Anyway, I would love to hear stories from anyone out there who are sharing a similar experience to me. And as always, best wishes to you all struggling with these nasty GI illnesses!

Read Steven's story at [www.dba.org/Steven-Story](http://www.dba.org/Steven-Story).

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Occasionally, specific products are cited in articles or acknowledgments. However, no endorsement is intended or implied. Our intention is to focus on overall treatment or management issues or strategies.

The articles in *Digestive Health Matters* are in no way intended to replace the knowledge or diagnosis of your doctor. We advise seeing a physician whenever a health problem arises requiring an expert's care.

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