



DigestiveHealth Matters

Participate in Your Own Health Care | Vol. 24, No. 2, ©2015 IFFGD

Highlights in this Issue

Assessing Risk as Well as Benefit
Weighing Both When Considering Treatment

August is Gastroparesis Awareness Month
Learn the Symptoms

Advocacy for FGIMD Research
*Rep. Sensenbrenner Asks Colleagues
to Cosponsor H.R. 2311*

Medical Research & Industry Treatment News
*Understanding GI Conditions;
New and Developing Therapies*

From the Community
*Strum For Your Tum, Raising Awareness
and Funds for GI Health*

DigestiveHealth Matters

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Our Unique Mission: The International Foundation for Functional Gastrointestinal Disorders (IFFGD) is a nonprofit education and research organization dedicated to informing, assisting, and supporting people affected by gastrointestinal disorders. IFFGD has been working since 1991 with patients, families, physicians, practitioners, investigators, employers, regulators, and others to broaden understanding about gastrointestinal disorders and support research.

International Foundation for
Functional Gastrointestinal Disorders



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“Adversity keeps trying to make our acquaintance; we just keep refusing to shake its hand!”

— DHA gastroparesis advocate Deb

Read Deb’s story at: www.dha.org/raise-awareness/stories/2227/deb

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Assessing Risk as Well as Benefit in Treatments

The goal of taking a drug to treat an illness is to help us feel better. When we are ill and looking for relief, the benefit of a treatment is usually the focus. We hear about the benefits of treatments from advertising and we go to see doctors looking for benefits. But, what about the risk that comes with it? When considering a treatment, you will want to understand and consider risk as well as benefit.

Any medicine – prescription, over-the-counter (OTC), and herbal – can have risks as well as benefits. Benefits are the helpful effects that you get from a drug or other therapy. Risks are the chances that something unwanted or unexpected, an adverse event or side effect, could happen to you. A side effect could be a minor nuisance or a serious event. Sometimes a side effect is unavoidable to achieve a treatment's benefits.

Understanding and managing risk is an important part of a long-term treatment plan. Taking an active role and working together with your physician gives the best chance for a positive outcome.

What You Can Do

As a patient, talk to your doctor about treatment risk as well as benefit. Here are some examples of questions to ask and things to consider:

- How severe is your own condition? What effect is it having on your life?
- What is the possible benefit from the drug being prescribed or suggested to you?
- In the context of your personal illness status, what are the chances that you will receive benefit from the treatment?
- How much benefit should you reasonably expect?
- What possible side effects might there be from the treatment?
- In the context of your personal health status, what are the chances that you will experience a side effect or serious adverse event from the treatment?
- What can you do to reduce the chances of side effects?
- How will you know when a side effect occurs?
- Exactly what should you do if a side effect occurs?



What to Expect from Your Healthcare Professional

People managing chronic illnesses do best medically when they work in partnership with their physician. Good communication between you and your doctor is essential. Here are ways your doctor may help you assess risk and benefit of a treatment as you work to manage your condition.

- Help educate you to understand your disorder, including its natural progression, and treatment options
- Help you have reasonable ideas about the level of benefit your treatment may achieve, and the risk associated with the treatment
- Explain factors that affect both risk and benefit – like prior medical history, multiple medications, or lifestyle choices
- Explain your risks, including what they are and how to reduce them, how to recognize side effects or adverse events, and what to do when they occur

Gaining a Better Understanding

It is important to be knowledgeable about benefit and risk of a treatment. There are no cures for functional GI or motility disorders. While the search for improved treatment options continues, we must do our best to understand current therapies. An understanding that all medications have inherent risks helps to best be able to consider treatment options, seek to learn how to manage risk, and achieve positive results. ■

Medical News Update

Hypnosis Therapy for GERD

A pilot study of 9 mostly female patients with functional heartburn found that esophageal directed hypnotherapy performed weekly over seven weeks was associated with improvement in heartburn symptoms and quality of life suggesting the use of hypnotherapy in functional heartburn patients who do not respond to standard drug therapies or who would prefer a non-pharmacologic lifestyle intervention.

Source: Riehl ME, et al. Feasibility and acceptability of esophageal-directed hypnotherapy for functional heartburn. *Dis Esophagus*. 2015 Mar 30. [Epub ahead of print]

Biomarker Advances for IBS

Two antibodies evident in a blood test appear helpful as biomarkers for differentiating a diagnosis of IBS from inflammatory bowel disease (IBD) in subjects with chronic diarrhea. The antibodies form in people who experience a bout of a GI infection (gastroenteritis), and about 10% of these individuals later develop what's termed post-infection IBS (PI-IBS). It is estimated that 6–17% of people with IBS have PI-IBS.

Source: Pimentel M, et al. Development and validation of a biomarker for diarrhea-predominant irritable bowel syndrome in human subjects. *PLoS One*. 2015 May 13;10(5):e0126438.

Nocturnal GERD Linked to Non-Infectious Rhinitis

A prospective 10-year study of 5,417 participants found that nighttime gastroesophageal reflux disease (GERD) appears to be a risk factor for non-infectious rhinitis/rhinosinusitis (NIR)

when adjusted for other known risk factors such as age, gender, body mass index, tobacco use, and asthma. NIR is associated with symptoms of stuffy nose, runny nose, and/or sneezing in the absence of the common cold.

Given these results the researchers recommend that individuals with rhinitis be assessed for GERD.

Source: Schioler L, et al. *Allergy*. 2015 March.

Homeopathic Medicines to Receive Greater Scrutiny from the FDA?

During a series of public hearings, the U.S. Food and Drug Administration (FDA) took testimony on whether or not it should regulate natural preparations – derived from plants, minerals, and animals – in the same way it does over-the-counter drugs. If the FDA decides in favor of stiffer regulations, homeopathic products would have to demonstrate safety and effectiveness before they could go to market. The FDA would also have the power to review the products' labeling and to reject false or misleading claims.

Currently, homeopathic products are allowed to be sold without pre-market review of approval by the FDA. Over the past several decades, the market for homeopathics has boomed to become a multi-billion dollar industry, and concerns over safety have grown. Since 2009, the FDA has issued almost 40 warning letters regarding the safety of certain homeopathic products.

Source: *FDA Public Hearing on Homeopathic Products Regulation Testimony*. May 20, 2015.

A Medical Food may Improve IBS Symptoms

Researchers in a small study that followed 14 patients with various forms of IBS concluded that oral serum-derived bovine immunoglobulin/protein isolate (SBI) as a medical food provides a safe option for patients with IBS-D but may have application in other forms of IBS. When directly questioned, 12 of the 14 patients indicated some level of overall improvement within 4 weeks after the addition of SBI to their standard therapy.

Source: Good L, et al. *World J Gastroenterol*. 2015 March.

Individuals with Fibromyalgia at Greater Risk for IBS

A study of 33,729 individuals with newly diagnosed fibromyalgia and 134,915 healthy controls randomly sampled from the Taiwan National Health Insurance Research Database between the years 2000 and 2011 found that presence of fibromyalgia was a significant risk factor for irritable bowel syndrome (IBS) when controlled for other factors, including sex, age, and the presence of other diseases. Treatment of fibromyalgia with antidepressants was also found to be a risk factor for IBS. Lastly, coexistence of certain other diseases along with fibromyalgia, including chronic liver or kidney disease, depression, anxiety, and sleep disorder was found to significantly increase risk for IBS.

From these findings the researchers suggest that individuals with fibromyalgia should be assessed regularly for other potential risk factors for IBS to reduce incidence.

Source: Yang TY, et al. *Medicine*. 2015 March.



Microbes Linked to the Production of Serotonin

Results of a laboratory study suggest that certain bacteria in the gut play an important role in regulating production of the chemical neurotransmitter serotonin. While serotonin is commonly recognized as a signaling molecule in the brain, it is estimated that 90% of the body's serotonin is produced by cells in the gastrointestinal (GI) tract. Altered levels of serotonin in the gut have been linked to several chronic diseases, including irritable bowel syndrome (IBS).

The role that intestinal bacteria play in the function of certain components of the gut nervous system promises to be an exciting direction for future research in the field of functional GI disorders.

Source: Yano JM, et al. *Cell*. 2015 April.

New Device Approved by FDA to Treat Silent Reflux

The U.S. Food and Drug Administration (FDA) has approved a non-invasive medical device (Reza Band) to treat symptoms in individuals with silent reflux (also called laryngopharyngeal reflux). Unlike in gastroesophageal reflux disease (GERD), in silent reflux gastric contents are regurgitated into the larynx (often called the “voice box”) and the pharynx. The device is worn while sleeping. It works by applying a slight pressure to the area below the Adam's apple, preventing the flow of gastric contents past the upper esophageal sphincter.

Symptoms of silent reflux include bothersome throat problems such as hoarseness, chronic cough, frequent throat clearing, and the sensation that something is stuck in the throat.

Source: *FDAnews.com*. 2015 March.

Biofeedback Therapy for Bowel Disorders

A joint American and European medical task force issued a position paper on the usefulness of biofeedback therapy for anorectal disorders. They concluded that, based on the strength of evidence, biofeedback therapy is recommended for short-term and long-term treatment of constipation with dyssynergic defecation and for the treatment of bowel incontinence. Several other specified uses were less strongly supported or not recommended.

The American Neurogastroenterology and Motility Society (ANMS) and the European Society of Neurogastroenterology and Motility (ESNM) examined available evidence in order to provide the recommendations.

Source: Rao SSC, et al. *Neurogastroenterol Motil*. 2015 May.

C. difficile Infection in the US

A 2011 survey estimated an incidence of *C. difficile* infection in the US of approximately 453,000 during the calendar year. Looking at a total of 15,461 active cases, the investigators found that two-thirds of *C. difficile* infections occurred in hospitals and nursing homes. Many infections were community-associated, meaning they happened among those who had not been inpatients in a health care facility. Common risk factors for *C. difficile* included female gender, Caucasian race, and being 65 years of age or older. More cautious prescribing of antibiotics and careful infection control in health care facilities can reduce the risk.

These results support the growing evidence that *C. difficile* is no longer

restricted to hospital and other inpatient settings. Understanding risk factors and patterns of infection is important in infection prevention and treatment planning. This study was performed as part of the U.S. Centers for Disease Control and Prevention (CDC) Emerging Infections Program (EIP).

Source: Lessa FC, et al. *N Engl J Med*. 2015 February.

New Recommendations Issued by the AGA on the Use of Endoscopes

The American Gastroenterological Association (AGA) has issued best-practices recommendations for physicians on the use of endoscopes, devices used to look inside a body cavity or organ. These recommendations together with the results of an upcoming U.S. Food and Drug Administration (FDA) Medical Devices Advisory Committee meeting will ensure that endoscopes meet a higher level of safety.

Source: *AGA Press Releases*. March 23, 2015.

Disease Burden in IBS-C and CIC

In a U.S. population-based survey of 328 individuals with constipation predominant irritable bowel syndrome (IBS-C) and 552 individuals with chronic idiopathic constipation (CIC), the researchers found that frequency and severity of symptoms were greater in IBS-C respondents than in respondents with CIC. However, in CIC respondents who also experienced frequent abdominal symptoms, such as pain and bloating, a similar disease burden to IBS-C respondents was evident.

Source: Heidelbaugh JJ, et al. *Am J Gastroenterol*. 2015 March. ■

News Reported at the 2015 Digestive Disease Week Meeting

Here are some brief reports on the research studies that were presented as summaries/abstracts at the 2015 Digestive Disease Week (DDW), an annual international conference for medical professionals.

The data and conclusions presented here should be considered *preliminary* until published in a peer-reviewed journal.

C. difficile

- In a preliminary study of 12 patients with recurrent *C-difficile* infection, fecal microbial transplantation was found to alter the antibiotic resistant profile of most recipients of the therapy to resemble the profile of the donor, and was maintained over time.

Celiac Disease

- 6
- When analyzed, of 15 different brands of popular probiotics labeled “gluten free,” 8 were found to contain gluten, including 2 that contained significant amounts (more than 20 parts per millions).
 - A survey of 12,187 patients with celiac disease compared to an equal number of healthy controls found that individuals with celiac disease had a higher prevalence of certain other chronic conditions, including IBS (8% compared to 1%).

Chronic Constipation

- An analysis of six randomized controlled studies demonstrated a consistent safety and efficacy profile for the drug prucalopride in the treatment of chronic constipation over 12 weeks in both men and women.
- In a randomized controlled study of 314 patients with chronic idiopathic constipation (CIC) with abdominal bloating, linaclotide (Linzess) compared to placebo was found to improve patient confidence in bowel movement success, completeness, ease, and patient ability to predict bowel movement timing.

Eosinophilic Esophagitis (EoE)

- Oral fluticasone, a steroid, was found to be an effective long-term maintenance therapy for EoE without growth impediment or serious side effects in 54 mostly male children for up to 5.7 years.
- A randomized controlled study of 93 adolescents and adults with EoE found that treatment with the steroid, oral budesonide suspension, improved symptoms of dysphagia and EoE more effectively than placebo after 12 weeks, with a good safety profile.

Gastroesophageal Reflux Disease (GERD)

- A 5-year follow-up analysis of 85 patients with GERD treated with the LINX magnetic antireflux device concluded that the device provides significant and durable reflux control with minimal side effects.
- Results from a random sample of 52 users of proton pump inhibitors (PPIs) compared with 52 controls, all over the age of 50, suggest that long-term (at least 5 continuous years) use of PPIs does not have a significant effect on bone strength.
- Researchers found a correlation between acid reflux and dental erosion in a sample of 27 children with reflux. By contrast, non-acid reflux was not associated with dental erosion.
- A survey of 94 patients reporting reflux symptoms, including heartburn, regurgitation, and the sensation of burning/pain in the chest found that about one-third with reflux symptoms resistant to standard therapies do not have GERD, but instead suffer from other disorders, most commonly functional heartburn.

Gastroparesis

- In an exploratory study involving 34 people with gastroparesis, an investigational drug, velusetrag (30 mg), was generally well tolerated and resulted in statistically significant improvement in gastric emptying time in both diabetic and idiopathic gastroparesis.



- In a study of people with gastroparesis or gastroparesis-like symptoms enrolled in the Gastroparesis Clinical Research Consortium (GpCRC) registry, of 92 treated with gastric electrical stimulation (GES) and 542 not treated with GES, those who underwent GES therapy were significantly more likely to show improvement in gastric symptoms at 48 weeks than those without GES treatment, suggesting more research be done in targeting GES therapy for gastroparesis patients not responding to standard medical approaches.
- Transcutaneous electrical acupuncture was found to effectively reduce symptoms of nausea and vomiting in 10 female patients with diabetic gastroparesis by altering neural activity.
- A survey that looked back at hospital admissions in the US for gastroparesis found that between the years 1997 and 2012 the number of inpatient admissions and the costs associated with these admissions have increased significantly, with the national costs for gastroparesis increased by 1,116.5%.

Irritable Bowel Syndrome (IBS)

- In a randomized controlled study of 75 patients with IBS on a low-FODMAP diet, adding gluten avoidance did *not* appear to offer additional symptom benefits and made it harder for patients to follow the diet.
- The presence and severity of abdominal bloating in a sample of 472 mostly female patients with IBS was found to be associated with increased sensation (visceral hypersensitivity) to intestinal contents, underscoring the importance of hypersensitivity as a target for treatment in patients with IBS.
- While dietary advice was found to be effective in reducing gastrointestinal symptoms of IBS in a sample of 67 patients, researchers found no clear difference between a low FODMAPs diet and traditional IBS dietary advice.
- A survey of 84 people with IBS and 226 healthy controls found that the IBS patients tend to have more widespread and severe non-gastrointestinal pain on average, most commonly headache (80%) and lower back pain (74%), which may point to a broader pain sensitization, but cannot account for increased levels of abdominal pain characteristic to IBS.

IBS in Children

- A randomized controlled study of 84 children with IBS found that treatment with psyllium fiber altered gut microbiome composition and reduced pain frequency more effectively than placebo.

IBS with Constipation (IBS-C)

- In a Phase 2 study of the drug tenapanor (50 mg), statistically significant improvement was seen in multiple symptoms of IBS-C over a 12-week period, with diarrhea the most common adverse effect.

IBS with Diarrhea (IBS-D)

- In a randomized controlled study among 72 mostly females patients with IBS-D or IBS-Mixed, a sustained release peppermint oil formulated to target release in the small intestine (IBgard®) was found to be statistically more effective than placebo in improving multiple IBS symptoms over a 4-week treatment period.
- A Phase 3 study of the drug ramosetron concluded that the drug improves multiple symptoms of IBS-D more effectively than placebo in both men and women.

Short Bowel Syndrome

- A pilot study of eight patients with short bowel syndrome with intestinal failure and jejunostomy found that treatment with the drug liraglutide may slow intestinal transit and increase intestinal energy absorption.

Small Bowel Adhesions

- A manually applied physical therapy protocol, focusing on deforming adhesions between and within the organs throughout the abdomen and pelvis, was found to be an effective treatment option in a sample of 26 patients with a history of small bowel adhesions, and was associated with improvement in reported symptoms including pain and overall quality of life. ■

Applying for Social Security Benefits for Your Child with a Gastrointestinal Disorder

By Deanna Power, Community Outreach Manager,
Disability Benefits Center

When a child is diagnosed with a severe gastrointestinal (GI) disorder, it can put financial strain on the family. Health threats like GI hemorrhage, inflammatory bowel disease, short bowel syndrome, or the need for parenteral feeding can result in one parent deciding to leave the workforce to care for the needs of the child. Such disorders can also result in costly medical care and high-priced qualified day care for the child. This can add to the financial struggle for many families. Fortunately, in some cases, Social Security Disability benefits are available to help offset the financial burden caused by a child's GI disorder.

SSI Benefits for Children with GI Disorders

The Social Security Administration is in charge of the Supplemental Security Income (SSI) program. SSI is for people with disabilities who have not worked throughout their lives. This needs-based program can help families overcome the financial hurdles that can be caused by a child's GI disorder.

In order for your child to qualify for SSI benefits, you must be able to prove to the Social Security Administration that your child has a condition that is listed in the SSA's Blue Book or that your child suffers from a condition that meets one of the listings that are contained within the publication. For example, if your child suffers from short bowel syndrome, the specific condition would be covered in Section 105.07 of the Blue Book. This particular section of the Blue Book states that your child will qualify for disability benefits if you can prove that your child suffers from short bowel syndrome due to a surgical resection of more than one-half of the small intestine, resulting in dependence on daily parenteral nutrition via a central venous catheter.

There are a number of GI disorders covered in the SSA Blue Book. Before applying for benefits for your child, it is important that you become familiar with which Blue Book listing your child qualifies so you know what medical documentation you will need in order to support your child's Social Security Disability claim.



Financially Qualifying for SSI Benefits

It is important to note that not all children who medically qualify for SSI benefits will qualify financially for these benefits, as the SSI program is a needs-based program. When applying for SSI benefits for your child, you will need to prove that your household meets the SSA's financial criteria. The SSA has a process, called "deeming," of determining how much of your income and resources will count as being available to your child. While only a portion of your household income will be deemed to the child when applying for benefits, families with substantial income will likely not qualify for SSI benefits. You can learn more about monthly income limits and SSI online at www.ssa.gov/ssi/text-child-ussi.htm.

Applying for SSI Benefits for Your Child

When you apply for SSI benefits for your child, you must make an appointment and apply in person at your local Social Security office. Unlike adult applications for SSI benefits, SSI applications for children cannot be completed online. When you go to your appointment, bring your child's medical records along with proof of financial eligibility, such as bank statements and pay stubs or income tax returns. The SSA has a Child Disability Benefit Starter Kit that can help parents prepare for their appointment. This can be found online at www.ssa.gov/disability/disability_starter_kits_child_eng.htm.

You will receive a notice regarding your child's application within two to four months of the application date. If for some reason your child is denied benefits, you have a right to appeal the denial. ■



Gastroparesis Awareness Month – *is August!*



Learn the Facts about Gastroparesis

Gastroparesis is a condition characterized by symptoms where the stomach does not empty properly. No obstruction or blockage is evident. Gastroparesis can occur in children or adults. In most people, the cause is unknown (idiopathic). See your healthcare provider if you are experiencing symptoms of gastroparesis. Learn more by visiting our website, www.aboutgastroparesis.org.

The symptoms of gastroparesis usually happen during or after eating a meal. They include:

- Nausea and/or vomiting
- Dry heaves
- Stomach fullness after a normal sized meal
- Early fullness – inability to finish a meal



www.aboutGastroparesis.org



IFFGD INDUSTRY COUNCIL

When 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

Sucampo Pharmaceuticals, Inc.
and Takeda Pharmaceuticals USA, Inc.

Salix Pharmaceuticals, Ltd.

QOL Medical, LLC.

NPS Pharmaceuticals, Inc.

Ironwood Pharmaceuticals, Inc.

Ferring International
PharmaScience Center US, Inc.

Entera Health, Inc.

Actavis

Seeking Participants with Diabetic Gastroparesis

Purpose of Study: To assess the safety of IW-9179 in individuals with diabetic gastroparesis and its effects on the principal symptoms of diabetic gastroparesis.

Sponsor: Ironwood Pharmaceuticals, Inc.

Study Population: Eligible male and female patients over the age of 18 and with a diagnosis of type 1 or type 2 diabetes mellitus and a diagnosis of diabetic gastroparesis.

Contacts: Find a recruiting location online at *ClinicalTrials.gov*; refer to *ClinicalTrials.gov* identifier: NCT02289846

Linacotide for Treatment of IBS-C

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 irritable bowel syndrome with constipation (IBS-C) or chronic idiopathic constipation (CIC). 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 abdominal pain.

Linacotide (Linzess) has been available in the U.S. to treat IBS-C and CIC in adults aged 18 and older since 2012. It is currently available in several European countries with the EU brand name Constella.

Linacotide should *not* be used in patients 17 years of age or younger or 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 Pharmaceuticals and Actavis. Ironwood has out-licensed linacotide to Almirall, S.A. for development in Europe; to Astellas Pharma for development in Japan, Indonesia, Korea, the Philippines, Taiwan, and Thailand; and to AstraZeneca in China.



Seeking Participants with Chronic Idiopathic Constipation for Trial of Linaclotide

Purpose of study: This 12-week, Phase 3 study will assess the efficacy and safety of linaclotide in patients with chronic idiopathic constipation (CIC).

Sponsor: Ironwood Pharmaceuticals, Inc.

Collaborator: Forest Laboratories

Participation: Eligible male and female patients demonstrating CIC aged 18 and older

Contacts: Find a recruiting location online at ClinicalTrials.gov; Refer to this study by its ClinicalTrials.gov identifier: NCT02291679

Recruiting for a Study on the Efficacy and Safety of Linaclotide for Opioid-Induced Constipation

Purpose of study: This 8-week, Phase 2, multicenter study will evaluate the safety and efficacy of linaclotide for the treatment of opioid-induced constipation (OIC) in adults receiving opioid treatment for chronic non-cancer pain.

Sponsor: Forest Laboratories

Collaborator: Ironwood Pharmaceuticals, Inc.

Participation: Eligible male and female patients 18 years and older who have presented chronic non-cancer pain for a minimum of 3 months and are receiving a stable dose of opioid treatment for at least 4 days.

Contacts: Kathy Hynek, phone: 866-369-5227, email: kathy.hynek@frx.com; Be sure to refer to this study by its ClinicalTrials.gov identifier: NCT02270983

Medical Food in the Management of Diarrhea

EnteraGam™ is a prescription *medical food* product to help people manage ongoing problems with chronic loose and frequent stools (diarrhea). Medical foods are required to be used under physician supervision as part of ongoing medical care for a specific condition or disease.

EnteraGam is manufactured and distributed by Entera Health, Inc. It is indicated for the clinical dietary management of intestinal disease (enteropathy) in patients who, because of therapeutic or chronic medical needs, have limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients.

The main ingredient in EnteraGam is a specially formulated protein preparation that consists of more than 50 percent of immunoglobulin (molecules involved with immune function). This ingredient, SBI (serum-derived bovine immunoglobulin/protein isolate), is made up of beef serum proteins. The proteins in SBI remain in the intestine and are not absorbed whole. EnteraGam is contraindicated for patients with a hypersensitivity (allergy) to beef, or any components in EnteraGam.

SBI may Improve IBS Symptoms

Researchers in a small study that followed 14 patients with various forms of IBS (2 IBS-C, 7 IBS-D, 2 IBS-Mixed, and 3 IBS-Undefined) concluded that SBI, oral serum-derived bovine immunoglobulin/protein isolate (EnteraGam), as a medical food provides a safe option for patients with IBS-D, but may have application in other forms of IBS. Twelve of the 14 patients indicated some level of overall improvement within 4 weeks after the addition of SBI to their standard therapy. The study results were published in March 2015 in the *World Journal of Gastroenterology*.

Review Looks at Effects of SBI on Managing Conditions like IBS-D

A review, which summarizes accumulated data from prior studies, concluded that specially formulated immunoglobulin sources like SBI have multiple effects which collectively serve to improve and maintain nutrient utilization, including water balance. This aids in the management of intestinal disorders (enteropathy) in patients with chronic loose and frequent stools in conditions like irritable bowel syndrome with diarrhea (IBS-D).

The mode of action appears to be combined effects on inflammation, gut barrier function, and immune balance. The study review, by Petschow et al, was published in August 2014 in the journal, *Digestive Diseases and Sciences*. The authors are employed by Entera Health.

Study Evaluates Impact of SBI in People with IBS-D

Results from a randomized, double-blind, placebo-controlled pilot study suggest that nutritional therapy with SBI, the ingredient found in EnteraGam – used in addition to traditional medical care – can help manage various symptoms associated with irritable bowel syndrome with diarrhea (IBS-D). The study, by Wilson et al., was published in 2013 in the journal, *Clinical Medicine Insights: Gastroenterology*.

A total of 45 persons completed the study per the protocol, with 31 in the SBI group and 14 in a placebo group. The symptom profile of each participant was determined during the first week, followed by a six-week treatment period. The safety profile of SBI in the study was similar to that of placebo.

The study showed that nutritional therapy with either 10 g/day or 5 g/day of SBI in patients was well tolerated and resulted in statistically significant improvements

in days with symptoms and a trend for improvement in symptom severity scores in participants with IBS-D. In particular, the 15 participants who received 10 g/day of SBI showed significant reductions in abdominal pain, loose stools, bloating, flatulence, and urgency.

Participants Sought for Congenital Sucrase-Isomaltase Deficiency (CSID) Genetic Prevalence Study in Children with Chronic Diarrhea or Chronic Abdominal Pain

Congenital sucrase-isomaltase deficiency (CSID) is a rare genetic disorder that affects a person's ability to digest the sugars sucrose and maltose. Sucrose is found in fruits, and is also known as table sugar. Maltose is the sugar found in grains.

In this study, clinicians are looking at using two different tests to rule out CSID, which often causes chronic diarrhea and/or abdominal pain for at least 4 weeks, may qualify to participate in this study.

If your child is eligible, there is the potential for up to three doctor's office visits that could include: having the inside of cheeks swabbed to look for common CSID genetic mutations, taking a breath test, providing a medical history review, and completing a few questionnaires.

Purpose of Study: Determine the prevalence of CSID genetic variants in subjects 18 years of age or younger with a primary symptom of chronic idiopathic diarrhea or chronic abdominal pain without constipation.

Sponsor: QOL Medical, LLC

Collaborators: 19 Medical Centers located throughout the U.S.

Contact: Heather Elser, Ph.D., 919-832-4949, helser@qolmed.com. Refer to this study by its *ClinicalTrials.gov* identifier: NCT01914003.

Review Article Concludes that Bile Acid Transport Inhibitor Elobixibat is Effective in Treating Chronic Idiopathic Constipation

Elobixibat is a first-in-class compound under investigation by Ferring Pharmaceuticals for treatment of chronic idiopathic constipation (CIC), and for irritable bowel syndrome with constipation (IBS-C).

An article recently published in the journal *Therapeutic Advances in Gastroenterology* reviewed data that examined the mechanisms by which bile acids can affect symptoms in CIC and the role of the drug elobixibat in managing these symptoms. Bile acids are digestive juices that have a stimulating effect in the colon. Elobixibat reduces bile absorption in the small intestine. This stimulates bowel movements by increasing fluid secretions and motility in the colon.

The authors concluded that published research shows that elobixibat significantly affects the symptoms of CIC, with minimal and tolerable side effects.

FDA Approves Eluxadoline (Viberzi) for Treatment of IBS-D in Men and Women

On May 27, 2015 the U.S. Food and Drug Administration (FDA) approved eluxadoline (Viberzi™), a new drug treatment for irritable bowel syndrome with diarrhea (IBS-D) in adult men and women. Viberzi is taken orally twice daily with food. The drug activates receptors in the nervous system that can lessen bowel contractions.

Viberzi is a novel drug compound to treat diarrhea and abdominal pain associated with IBS-D. The safety and effectiveness

of the drug for treatment of IBS-D were established in two double-blind, placebo-controlled clinical trials in which 2,425 patients were randomly assigned to receive the eluxadoline or placebo. Results showed Viberzi was more effective in simultaneously reducing abdominal pain and improving stool consistency than placebo over 26 weeks of treatment.

In clinical trials the drug was generally well tolerated. The most common side effects in patients treated with Viberzi were constipation and nausea.

The most serious known risk associated with Viberzi is the risk of spasm in the sphincter of Oddi, the smooth muscle that surrounds the end portion of the common bile and pancreatic ducts, which can result in pancreatitis. Viberzi should *not* be used in patients with a history of bile duct obstruction, pancreatitis, severe liver impairment, or severe constipation, and in patients who drink more than three alcoholic beverages per day.

Viberzi has mixed opioid receptor activity. It is a mu receptor agonist, a delta receptor antagonist, and a kappa receptor agonist.

The FDA has recommended that Viberzi be classified as a controlled substance. This recommendation has been submitted to the U.S. Drug Enforcement Administration (DEA). Product availability is expected in early 2016.

Teduglutide Granted Orphan Drug Status in Japan

In January 2015 the Japanese Ministry of Health, Labor, and Welfare (MHLW) granted teduglutide (Gattex in the U.S.; Revestive in the E.U.) orphan drug status for the treatment of adult patients with short bowel syndrome (SBS).



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

In June 2014 the U.S. Food and Drug Administration (FDA) approved updated labeling for teduglutide (Gattex) for injection to include long-term data from adult patients with Short Bowel Syndrome (SBS). The revised labeling provides important information for healthcare professionals and patients about long-term use of teduglutide.

The data, published in 2013, demonstrated that there was an increased response to treatment over time in all groups receiving teduglutide. The open-label extension study included 88 adult patients with SBS. Investigators reported that the long-term use of teduglutide 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 teduglutide therapy. No new unexpected safety concerns were observed with long-term teduglutide 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.

Teduglutide was approved by the FDA as Gattex in 2012 for treatment of adult patients with SBS who are dependent on

parenteral support. To help ensure that the benefits of the drug 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.

Patients with SBS Sought for Long-term Study

Purpose of Study: This global clinical study is enrolling patients with short bowel syndrome (SBS) in order to provide additional long-term data on safety of teduglutide and on the natural history of SBS in patients in routine, real world settings. The information gathered is intended to assist health care providers in optimizing their clinical decision making in managing SBS patients.

Enrollment will include SBS patients treated and not treated with teduglutide.

Sponsor: NPS Pharmaceuticals, Inc.

Study Population: Male and female patients of any age with a diagnosis of SBS, including those who have never taken teduglutide, as well those who have or are using teduglutide.

Study Follow-up Duration: 10 years

Contact: NPS Clinical Operations, phone: 908-450-5300, email: SBSregistry@quintiles.com; Refer to [ClinicalTrials.gov](https://clinicaltrials.gov) identifier: NCT01990040

FDA Approves rifaximin (Xifaxan) for Treatment of IBS-D in Adults

On May 27, 2015 the U.S. Food and Drug Administration (FDA) approved the antibiotic rifaximin (Xifaxan®) 550 mg for treating irritable bowel syndrome with diarrhea (IBS-D) in adult men and women.

The safety and effectiveness of Xifaxan for treatment of IBS-D were established in three double-blind, placebo-controlled trials. In the first two trials, 1,258 patients were randomly assigned to receive Xifaxan or placebo for 14 days, and then followed for a 10-week treatment-free period. More Xifaxan-treated patients reported improvements in abdominal pain and stool consistency than those on placebo.

A third trial evaluated repeat courses of Xifaxan, because patients with IBS-D can develop recurrent signs and symptoms after a single treatment course of Xifaxan. A total of 636 patients with recurrence were randomized to receive either Xifaxan or placebo for two additional 14-day courses separated by 10 weeks. More patients treated with Xifaxan than placebo were responders in abdominal pain and stool consistency in this phase of the study.

Xifaxan works by reducing or altering bacteria in the gut. It is only slightly absorbed in the gut and is generally tolerated well. The most common side effects in patients treated with Xifaxan for IBS-D include nausea and an increase in alanine aminotransferase (ALT), a liver enzyme measured in blood.

If diarrhea does not improve or worsens after treatment with Xifaxan, then evaluation for development of *C. difficile* enterocolitis should be performed. Caution should be used when using Xifaxan in patients with severe liver impairment or when combined with certain other drugs.

Guidance Issued in U.K. for Amitiza in Treating Chronic Idiopathic Constipation

The National Institute for Health and Care Excellence (NICE) has issued guidance on the use of lubiprostone (Amitiza) for treating chronic idiopathic constipation in the United Kingdom. The guidelines stipulate that the drug should only be considered in adults who have tried at least 2 laxatives at the highest tolerated recommended doses for at least 6 months, but who have not seen an improvement in their symptoms. NICE clinical guidelines are recommendations on the appropriate treatment and care of people with specific diseases and conditions within the National Health Service (NHS) in the United Kingdom.

Lubiprostone Study Published Showing Efficacy in Opioid-Induced Constipation

A study published in 2014 in the medical journal *Pain Medicine* examined the efficacy and safety of lubiprostone (Amitiza) for relieving symptoms of opioid-induced constipation (OIC) in chronic non-cancer pain. The study found that patients treated with lubiprostone showed significant overall

improvement for abdominal discomfort, straining, constipation severity and stool consistency when compared to placebo. The authors concluded that lubiprostone was effective and well tolerated in OIC patients with chronic non-cancer pain.

Lubiprostone is a prescription drug first FDA approved in 2006 to relieve abdominal pain, bloating, and straining and produce softer and more frequent bowel movements in men and women who have chronic idiopathic constipation (CIC). It is also FDA approved to treat irritable bowel syndrome with constipation (IBS-C) in women who are at least 18 years of age. Lubiprostone works by increasing the amount of fluid that flows into the bowel and allowing the stool to pass more easily.

The drug was FDA approved in 2013 for the treatment of OIC in patients with chronic, non-cancer pain. Opioids (such as morphine and codeine) are narcotics used to treat pain. The effectiveness of lubiprostone has not been established in those taking methadone. 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.

Two Studies of Lubiprostone in Pediatric Subjects with Functional Constipation

Purpose of study 1: This is a 12-Week study to evaluate the efficacy, safety, and pharmacokinetics of oral lubiprostone as treatment for pediatric patients with functional constipation.

Collaborators: Sucampo Pharma Americas, LLC and Takeda

Participation: Eligible male and female patients aged 6–17 years

Contacts: Shadreck Mareya, PhD, phone: 301-961-3400, email: pedgen@sucampo.com; Refer to *ClinicalTrials.gov* identifier: NCT02042183

Purpose of study 2: This is a 9-Month study to evaluate the long-term safety, efficacy, and pharmacokinetics of oral lubiprostone as treatment for pediatric patients with functional constipation.

Collaborators: Sucampo Pharma Americas, LLC and Takeda

Participation: Eligible male and female patients aged 6–17 years

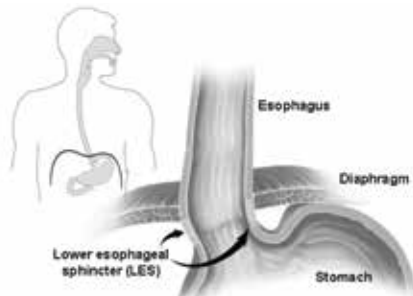
Contacts: Shadreck Mareya, PhD, phone: 301-961-3400, email: pedgen@sucampo.com; Refer to *ClinicalTrials.gov* identifier: NCT02138136 ■



Achalasia

Achalasia is a motility disorder in which the esophagus (food tube) empties slowly. The delay results from poor opening of the lower esophageal sphincter (LES) along with the loss of the normal, orderly muscle activity (peristalsis) that propels foods and liquids along the esophagus into the stomach.

Achalasia results from nerve damage in the esophagus and LES. Often the cause is unknown. Men and women are equally affected. It occurs in adults and children.



Symptoms of Achalasia

Symptoms of achalasia usually occur during and after a meal. A sensation of solids, and usually liquids, hanging up and passing slowly into the stomach may occur several times a week or at every meal.

Other common symptoms include effortless regurgitation of bland, undigested food or whitish foam (saliva) that may be associated with coughing and choking at night, and heartburn due to retained acidic food or the fermentation of food in the esophagus. About half of people with achalasia will lose weight.

Tests for Achalasia

The diagnosis of achalasia is suspected by barium x-rays and confirmed by esophageal manometry.

- Barium study of the esophagus (esophagram) involves x-rays after swallowing a contrast material (barium).
- Esophageal manometry involves placing a small tube with pressure sensors into the stomach, and slowly withdrawing while measuring lower esophageal valve pressure and peristalsis.

An upper GI endoscopy to exclude other disease as causing symptoms is often done. Endoscopy is a procedure that uses a thin, flexible tube with a light and a lens on the end to look into the esophagus and stomach.

Treatment of Achalasia

The goal of treating achalasia is to alter and open the LES to improve esophageal emptying and relieve symptoms. Presently, no treatment is available to promote the return of peristalsis.

The best treatments for healthy patients are pneumatic dilatation or laparoscopic Heller myotomy. Frail or elderly patients may do well with botulinum toxin (Botox) injections.

Treatment markedly relieves symptoms, but is rarely curative. Overall, the success of both the pneumatic dilation and heller myotomy procedures is 80%-90% and dependent on the skills of the operator. Retreatment may be required and alternative treatments may be needed.

- Pneumatic dilatation – This procedure involves upper GI endoscopy with the passage of various size balloons to tear the esophagus from within, opening the valve. The procedure is done with conscious sedation and takes about 30 minutes, with a loss of one day of activity. The major complication, esophageal perforation (hole in the esophagus), is rare (less than 5%), but will require major surgery.
- Heller myotomy – Surgery for achalasia involves cutting the muscle (myotomy) from the outside via small laparoscopic sites on the abdomen. The procedure requires general anesthesia, hospitalization for up to two days, and limited activity for two weeks. The major side effect is cutting the muscle too much, causing bad acid reflux.
- Botulinum toxin – Botox can be injected into the esophagus and lower esophageal valve, via a needle passed through an upper endoscope. The toxin relaxes the sphincter, and thereby relieves symptoms. In young patients, symptoms relief is generally for only 3-6 months, while older patients may have relief for one year or longer. Adverse events are rare.

Medications may also be tried to relax the lower esophageal sphincter when surgery or pneumatic dilation is not an option, or Botox therapy has failed. Calcium channel blockers and long-acting nitrates are commonly used. ■

U.S. Professional Events

10TH POSTGRADUATE COURSE – GASTROINTESTINAL MOTILITY & NEUROGASTROENTEROLOGY IN CLINICAL PRACTICE

When: August 28, 2015

Location: Chicago, IL

Organizer: American Neurogastroenterology and Motility Society (ANMS)

Website: www.motilitysociety.org/abstract_instructions.php

VISIT IFFGD AT THIS EVENT!

JAMES W. FRESTON CONFERENCE – A RENAISSANCE IN THE UNDERSTANDING AND MANAGEMENT OF IBS

When: August 29 & 30, 2015

Location: Chicago, IL

Organizer: American Gastroenterological Association

Website: www.gastro.org/education-meetings/live-meetings/james-w-freston-conference/2015-james-w-freston-conference-a-renaissance-in-the-understanding-and-management-of-ibs

PRIM-ED REGIONAL CONFERENCE: WEST

When: September 9-10, 2015

Location: San Jose, CA

Organizer: Prim-Ed

Website: www.pri-med.com/regional-conferences

PRIM-ED REGIONAL CONFERENCE: EAST

When: September 11, 2015

Location: Raleigh, NC

Organizer: Prim-Ed

Website: www.pri-med.com/regional-conferences

ASPMN 25TH NATIONAL CONFERENCE

When: September 16-19, 2015

Location: Atlanta, GA

Organizer: American Society for Pain Management Nursing (ASPMN)

Website: www.aspmn.org/calendar

AMERICAN ACADEMY OF FAMILY PHYSICIANS ANNUAL MEETING

When: September 29-October 3, 2015

Location: Denver, CO

Organizer: American Academy of Family Physicians

Website: www.aafp.org/events

FOOD & NUTRITION CONFERENCE & EXPO

When: October 3-6, 2015

Location: Nashville, TN

Organizer: Academy of Nutrition and Dietetics

Website: www.eatright.org/fnce/

PRIM-ED REGIONAL CONFERENCE: SOUTH

When: October 7

Location: Houston, TX

Organizer: Prim-Ed

Website: www.pri-med.com/regional-conferences

NASPGHAN 2015 ANNUAL MEETING AND POSTGRADUATE COURSE

When: October 7-10, 2015

Location: Washington, D.C.

Organizer: North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN)

Website: www.naspghan.org/content/3/en/Meetings

BEHAVIORAL AND REHABILITATION TREATMENT OF BOWEL DISORDERS – AN ADVANCED COURSE

When: October 15-17, 2015

Location: Milwaukee, WI

Organizer: Marquette University

Website: www.marquette.edu/health-sciences/continuing-ed-boweldisorder/

ACG 2015 ANNUAL SCIENTIFIC MEETING AND POSTGRADUATE COURSE

When: October 16-21, 2015

Location: Honolulu, HI

Organizer: American College of Gastroenterology (ACG)

Website: www.gi.org/event/acg-2012-annual-scientific-meeting-postgraduate-course/

PRIM-ED REGIONAL CONFERENCE: SOUTHEAST

When: October 22

Location: Ft. Lauderdale, FL

Organizer: Prim-Ed

Website: www.pri-med.com/regional-conferences

PRIM-ED REGIONAL CONFERENCE: MIDWEST

When: November 6, 2015

Location: Indianapolis, IN

Organizer: Prim-Ed

Website: www.pri-med.com/regional-conferences

PRIM-ED REGIONAL CONFERENCE: WEST

When: November 10-11, 2015

Location: Los Angeles, CA

Organizer: Prim-Ed

Website: www.pri-med.com/regional-conferences

PRIM-ED REGIONAL CONFERENCE: NORTHEAST

When: November 19-20

Location: New York, NY

Organizer: Prim-Ed

Website: www.pri-med.com/regional-conferences

PRIM-ED REGIONAL CONFERENCE: EAST

When: December 8-9, 2015

Location: Baltimore, MD

Organizer: Prim-Ed

Website: www.pri-med.com/regional-conferences

PRIM-ED REGIONAL CONFERENCE: SOUTHEAST

When: December 8-9, 2015

Location: Tampa, FL

Organizer: Prim-Ed

Website: www.pri-med.com/regional-conferences

ASPMN 26TH NATIONAL CONFERENCE

When: September 7-10, 2015

Location: Louisville, KY

Organizer: American Society for Pain Management Nursing (ASPMN)

Website: www.aspmn.org/calendar

ACG 2016 ANNUAL SCIENTIFIC MEETING AND POSTGRADUATE COURSE

When: October 14-19, 2016

Location: Las Vegas, NV

Organizer: American College of Gastroenterology (ACG)

Website: <http://www.gi.org/>

GASTRO 2017 ACG-WGO INTERNATIONAL CONGRESS

When: October 13-18, 2017

Location: Orlando, FL

Organizer: American College of Gastroenterology (ACG) and World Gastroenterology Organization (WGO)

Website: www.gi.org/education-and-meetings/acg-annual-meeting-and-postgraduate-course/



International Professional Events

PARAGUAYAN XII CONGRESS OF GASTROENTEROLOGY AND DIGESTIVE ENDOSCOPY – DAY OF DISEASES

When: July 22-24, 2015
Location: Asuncion, Paraguay
Organizer: Sociedad Paraguaya de Gastroenterologia
Website: www.spge.org.py

CONGRESS OF GASTROENTEROLOGY CHINA (CGC)

When: September 4-6, 2015
Location: Tianjing, China
Organizer: Chinese Society of Gastroenterology
Website: www.csge.org/

ARGENTINE CONGRESS OF GASTROENTEROLOGY AND DIGESTIVE ENDOSCOPY 2015

When: September 17-19, 2015
Location: Tucuman, Argentina
Organizer: Federacion Argentina de Gastroenterologia (FAGE), Sociedad Argentina de Gastroenterologia (SAGE), and Federacion Argentina de Asociaciones de Endoscopia Digestiva (FAAED)
Website: www.gastro2015.com.ar

XXV CENTRAL AMERICAN AND CARIBBEAN CONGRESS OF GASTROENTEROLOGY AND DIGESTIVE ENDOSCOPY AND THE XXIV CONGRESS DOMINICAN GASTROENTEROLOGY

When: September 17-20, 2015
Location: Punta Cana, Dominican Republic
Organizer: Federacion Argentina de Gastroenterologia (FAGE), Sociedad Argentina de Gastroenterologia (SAGE), and Federacion Argentina de Asociaciones de Endoscopia Digestiva (FAAED)
Website: www.sodogastro.com

GASTRO 2015 AGW/WGO INTERNATIONAL CONGRESS

When: September 28-October 2, 2015
Location: Queensland, Australia
Organizer: Gastroenterological Society of Australia and World Gastroenterology Organization
Website: www.worldgastroenterology.org/

ANNUAL MEETING SGGO–SGVC–SASL 2015

When: October 1-2, 2015
Location: Switzerland
Organizer: Swiss Society of Gastroenterology

(SGG), Swiss Society of Visceral Surgery (SGVC), Swiss Association for the Study of the Liver (SASL), and Swiss Society of Endoscopy Nurses and Associates (SSNA)
Website: www.sgg-sgvc-congress.ch

7TH CONGRESS OF THE CROATIAN SOCIETY OF GASTROENTEROLOGY

When: October 1-4, 2015
Location: Opatija, Croatia
Organizer: Croatian Society of Gastroenterology
Website: www.hgd.hr

3RD SERBIAN GASTROENTEROLOGY CONGRESS

When: October 8-10, 2015
Location: Belgrade, Serbia
Organizer: Association of Serbian Gastroenterologists (ASG)
Website: www.ugs.rs

JDDW 2015

When: October 8-11, 2015
Location: Tokyo, Japan
Organizer: Organization of the Japan Digestive Disease Week (JDDW)
Website: www.jddw.jp/jddw2015/en/index.html

XXI RUSSIAN GASTROENTEROLOGICAL WEEK

When: October 12-14, 2015
Location: Moscow, Russia
Organizer: Russian Gastroenterological Association
Website: www.gastro.ru

UNITED EUROPEAN GASTROENTEROLOGY WEEK (UEGW)

When: October 24-28, 2015
Location: Barcelona, Spain
Organizer: United European Gastroenterology
Website: www.ueg.eu/week/

33RD CZECH AND SLOVAK CONGRESS OF GASTROENTEROLOGY

When: November 12-14, 2015
Location: Prague, Czech Republic
Organizer: Czech Society of Gastroenterology
Website: www.gastropraha2015.cz

56TH ANNUAL CONFERENCE OF THE INDIAN SOCIETY OF GASTROENTEROLOGY

When: November 19-22, 2015
Location: Indore, India
Organizer: Indian Society of Gastroenterology
Website: www.isgcon2015.org

14TH BRAZILIAN DIGESTIVE WEEK

When: November 21-25, 2015
Location: Parana, Brazil
Organizer: Pederacao Brasileira de Gastroenterologia, Sociedade Brasileira de Endoscopia Digestive (SOBED), and Colegio Brasileiro de Cirurgia Digestiva (CBCD)
Website: www.sbad2015.com.br

NZSG ANNUAL SCIENTIFIC MEETING 2015

When: November 25-27, 2015
Location: Rotorua, New Zealand
Organizer: New Zealand Society of Gastroenterology
Website: www.gastro2015.com.nz

XLII CHILEAN CONGRESS OF GASTROENTEROLOGY

When: November 25-27, 2015
Location: Vina del Mar, Chile
Organizer: Sociedad Chilena de Gastroenterologia (SCHGE)
Website: www.sociedadgastro.cl

APDW 2015

When: December 3-6, 2015
Location: Taipei, Taiwan
Organizer: Asian Pacific Association of Gastroenterology
Website: www.apdw2015.org/

JDDW 2016

When: November 3-6, 2016
Location: Kobe, Japan
Organizer: Organization of Japan Digestive Disease Week (JDDW)
Website: www.jddw.jp/english/index.html/

WORLD CONGRESS OF PEDIATRIC GASTROENTEROLOGY, HEPATOLOGY, AND NUTRITION

When: November 5-8, 2016
Location: Montreal, Canada
Organizer: Federation of the International Societies of Pediatric Gastroenterology, Hepatology, and Nutrition
Website: www.fispgban.org/

GASTRO 2016 EGHS–WGO INTERNATIONAL CONGRESS

When: November 17-19, 2016
Location: Abu Dhabi, UAE
Organizer: Emirates Gastroenterology and Hepatology Society (EGHS) and World Gastroenterology Organization (WGO)
Website: www.gastro2016.com/ ■

In June, Representative F. James Sensenbrenner, Jr. (WI-5) circulated the following Dear Colleague letter to invite other House Members of Congress to cosponsor *The Functional Gastrointestinal and Motility Disorders Research Enhancement Act* of 2015 (H.R. 2311):

SUPPORT H.R. 2311, THE FUNCTIONAL GASTROINTESTINAL AND MOTILITY DISORDERS RESEARCH ENHANCEMENT ACT

From: The Honorable F. James Sensenbrenner, Jr. Sent By: Erik.Kinney@mail.house.gov
Bill: H.R. 2311

Date: 6/18/2015

Dear Colleague:

Functional gastrointestinal (GI) and motility disorders refer to medical conditions where normal movement of the digestive tract, sensitivity of the nerves of the digestive tract, or the way in which the brain controls some of these functions is impaired. These conditions affect two in five Americans, cause considerable suffering and disability, and cost society over \$30 billion annually. They can affect any area of the digestive tract and are characterized by persistent recurring symptoms that cause tremendous personal and societal burden.

These disorders remain poorly understood and additional awareness, education, and research are needed to help improve patients' health outcomes. One such functional GI disorder, irritable bowel syndrome (IBS), often leads to unnecessary surgery. Although surgery is not a treatment for IBS, compared to persons without IBS, patients with IBS are 3 times more likely to have gallbladder removal surgery and 2 times more likely to have an appendectomy or hysterectomy, exposing them to surgically-related morbidity and even mortality.

Functional GI disorders are part of the spectrum of Chronic Multisymptom Illness (also called Gulf War Syndrome), which affects veterans who served in the Southeast Asia Theater of Operations during the Gulf War. In Gulf War Veterans who meet diagnostic criteria for a functional GI disorder, the Department of Veterans Affairs (VA) recognizes a presumption of service connection in order for them to receive VA disability compensation.

In an effort to support the population affected by gastrointestinal disorders, I have introduced the *Functional GI and Motility Disorders Research Enhancement Act* (H.R. 2311), which will immensely benefit individuals who suffer from various functional GI and motility disorders by advancing our scientific understanding of these disorders and improving treatments options for patients.

We invite all colleagues to join us in the fight against these devastating diseases by becoming a co-sponsor of H.R. 2311. Through co-sponsorship your support will work to promote awareness of functional GI and motility disorders, the need for expanded research at the National Institutes of Health (NIH), and progress of effective therapies at the Food and Drug Administration (FDA) for this vulnerable patient population. Please contact Erik Kinney with Rep. Sensenbrenner at Erik.Kinney@mail.house.gov or 202-225-5101 to cosponsor the legislation.

Sincerely,

F. JAMES SENSENBRENNER (R-WI)
Member of Congress

Ask your Representative to Cosponsor H.R. 2311

You can take action to ask your Congressional Representative to support *The Functional GI and Motility Disorders Research Enhancement Act* of 2015!

Call the U.S. Capitol Switchboard at (202) 225-3121 and ask to be connected to your Representative's office. Identify yourself as a constituent who would like to speak with the staff member responsible for health issues. Ask that your Congressional Representative become a cosponsor of H.R. 2311, *The Functional Gastrointestinal and Motility Disorders Research Enhancement Act*.

Quick Facts about H.R.2311

1. H.R. 2311 is *revenue-neutral*; it does not require additional costs to implement.
2. Functional gastrointestinal and motility disorders affect 1 in 4 people in the U.S. – men, women, and children.
3. The conditions are a serious issue for many military veterans – part of Chronic Multisymptom Illness (or Gulf War Syndrome).
4. The conditions involve improper functioning of the nerves, muscles, and related mechanisms of the digestive tract.
5. They are chronic and can be life-threatening.
6. These conditions are often misdiagnosed and mistreated.
7. Currently, treatment options are extremely limited, not always effective, and focus on symptom management – no cures are known.



PCG Account Manager Runs “Strum For Your Tum” Event

By Denise Casagrande

On June 14th, Kristen Chiarello ran a successful fundraiser in Staten Island, N.Y. Kristen, an Account Manager at PCG, took on the Strum For Your Tum event: an event that raises awareness and money for the Digestive Health Alliance. The DHA is a grassroots arm of the International Foundation for Functional Gastrointestinal Disorders (IFFGD), a nonprofit organization dedicated to improving the quality of life of those affected by these chronic digestive issues.

This foundation hits close to home for Kristen. She herself has been battling digestive issues for 20 years, as well as her mother, sister, and daughter. Currently there is no cure, and medications can sometimes cause difficult side effects. Kristen is pleased to have been able to find a foundation that is set up to help with digestive problems, because there are so many people suffering without the proper knowledge and resources they so badly need.

The Strum For Your Tum fundraiser was a four-hour live music and raffle held at Play Sports Bar & Restaurant. The event was outdoors with the musical talents of 2 Easy and Pair of Dolls headlining the event. Attendees were able to dance and enter to win the 50/50.

Through this, Kristen learned that she loves running events. “It’s always great to see that many places and people are willing to give for a good cause,” she said, “and of course, who doesn’t love raffles!” She is thrilled with the success of the day and the awareness that was raised. Her favorite part of the event was by far the musical talent — and the attendees agreed. They were blown away by the performances.

Considering running an event? Here is Kristen’s advice:

1. Organization and planning is key.
2. Get really good raffle items so that people will buy tickets.
3. Enlist the help of family and friends to help the day run smoothly.
4. Don’t stress the day of the event: it’s all for fun and for a good cause!

We’re very proud of Kristen and her accomplishment!
To learn more about DHA, visit www.dha.org. ■



Photo Credit: Denise Casagrande



Photo Credit: Lori Doll Photography



Photo Credit: John Posada

This article was originally written for the PC Digital Marketing blog.

Find the original article on the Strum for Your Tum fundraising page at: www.dha.org/dw/funraisers/1063.

INTERNATIONAL FOUNDATION FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

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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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This issue of *Digestive Health Matters* is sponsored, in part, by Actavis, Ironwood Pharmaceuticals, Inc., and donors to IFFGD.

Our Unique Mission: The International Foundation for Functional Gastrointestinal Disorders (IFFGD) is a nonprofit education and research organization dedicated to informing, assisting, and supporting people affected by gastrointestinal disorders. IFFGD has been working since 1991 with patients, families, physicians, practitioners, investigators, employers, regulators, and others to broaden understanding about gastrointestinal disorders and support research.



International Foundation for
Functional Gastrointestinal Disorders
IFFGD

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