



International Foundation for
Functional Gastrointestinal Disorders

IFFGD

Information. Assistance. Support.

DigestiveHealth Matters

Participate in your own health care | Vol. 21, No. 3, © 2012 IFFGD

- 2 Highlights in this issue**
- 3 GERD Awareness Week**
- 4 Surgical Treatment of GERD**
- 8 How to Get the Most from Your Doctor Visit**
- 9 Books of Interest**
- 11 Treatment News**
- 15 Professional Announcements**
- 16 Community News**
 - Looking Ahead to the 113th Congress**
 - Awareness Walk for Gastroparesis**
 - FDA Testimony on Short Bowel Syndrome**
 - Seeking Cures**
 - Taking Action**

Highlights in this issue

Feature Articles

A review of treatments for GERD by Andrew S. Kastenmeier, M.D. and Jon Gould, M.D. that takes a close look at the surgical option.

Plain-language publications from the U.S. Department of Health and Human Services' Agency for Healthcare Research and Quality (AHRQ) compare the benefits and risks of treatments for gastroesophageal reflux disease (GERD).

Tips on how to get the most from your doctor visit, help make sense of treatment options, and improve communication with your doctor.

Research and Treatment News

FDA approval given to linaclotide (Linzess) to treat irritable bowel syndrome with constipation (IBS-C) and chronic constipation (CC) in adults aged 17 and older.

The European Committee for Medicinal Products for Human Use (CHMP) recommended the marketing approval for linaclotide for the treatment of moderate to severe irritable bowel syndrome with constipation (IBS-C) in adults.

Solesta, a bulking agent for the treatment of bowel incontinence is now available in the U.S. through experienced and certified physicians.

Patient enrollment has begun for clinical trials looking at retreatment with rifaximin, an antibiotic under investigation to treat non-constipation IBS.

A study of lubiprostone (Amitiza) concluded that the drug is safe and well tolerated over 9–13 months of treatment in patients with IBS with constipation.

The U.K. Medicines and Healthcare Products Regulatory Agency approved lubiprostone (Amitiza) for the treatment of chronic idiopathic constipation and associated symptoms in adults, when response to diet and other non-pharmacological measures are inappropriate.

The FDA has given priority review to lubiprostone for the treatment of opioid-induced constipation (OIC) in patients with chronic, non-cancer pain. FDA's decision is expected by late January 2013.

The FDA Gastrointestinal Drugs Advisory Committee voted unanimously to recommend approval of Gattex for adults with short bowel syndrome (SBS). The drug is currently under review by the FDA, which is expected to make a final decision on the drug by the end of 2012.

Patient enrollment has begun for Phase 3 clinical trials looking at a drug under investigation to treat IBS with diarrhea, MuDelta (JNJ-27018966).

IFFGD is reviewing applications from active investigators for 2013 Research Awards.

Community News

Your action is needed to help continue to make the Functional GI and Motility Disorders Research Enhancement Act law in the new 113th Congress.

The first annual Awareness Walk for Gastroparesis (GP) in Bellingham, WA was a great success raising nearly \$3,000 for the Digestive Health Alliance to support research.

IFFGD provided written testimony to the FDA regarding patient needs in connection with the October meeting of the GI Drugs Advisory Committee considering the new drug application for Gattex to treat short bowel syndrome.

Q&A – What do you say? I would like to see a cure for _____ because _____.





GERD

Awareness Week

November 18-24, 2012

Frequent heartburn or indigestion may be a symptom of gastroesophageal reflux disease, or GERD.

GERD is a disease that can be treated. Unrecognized or untreated, GERD can lead to serious complications.

Don't let GERD interfere with your daily life. Talk to your doctor for an accurate diagnosis.

To learn more, contact IFFGD.

IFFGD, the International Foundation for Functional Gastrointestinal Disorders, is a nonprofit organization that provides digestive health information and support.

Visit our web site at www.aboutgerd.org

Did you know – Heartburn is not the only symptom of GERD.

Chronic heartburn is the most common symptom of GERD. Refluxed material into the mouth is another common symptom. But other less common symptoms may be associated with GERD.

These include:

- Belching
- Difficulty swallowing
- Sudden excess saliva
- Feeling like food is getting stuck
- Chronic sore throat
- Laryngitis
- Inflammation of the gums
- Erosion of tooth enamel
- Chronic irritation of the throat
- Hoarseness in the morning
- A sour taste
- Bad breath



The Surgical Treatment of Gastroesophageal Reflux Disease (GERD)

By: Andrew S. Kastenmeier, M.D., and Jon Gould, M.D., Division of General Surgery, Medical College of Wisconsin, Milwaukee, WI

Gastroesophageal reflux disease (GERD) is defined as the back-flow of stomach contents into the esophagus causing undesirable symptoms and potentially resulting in esophageal damage.

Symptoms of GERD

The most common symptom of GERD is heartburn. This is an uncomfortable burning sensation felt in the middle of the upper abdomen and/or lower chest. Other typical symptoms include difficulty swallowing (dysphagia) and regurgitation of fluid into the esophagus. In some cases fluid may even reflux into the mouth. People with GERD also may develop other, atypical (extra-esophageal) symptoms such as hoarseness, throat-clearing, sore throat, wheezing, chronic cough, and even asthma. Many persons suffer from extra-esophageal reflux symptoms for quite some time before a causal relationship with GERD is established. This is at least partly related to the fact that there are many other causes for these kinds of symptoms other than GERD.

In many people, there is no obvious reason for failure of the LES. The LES itself may be weak or its supporting structures (from the esophagus, the diaphragm, or the angle the esophagus enters the stomach) may be inadequate. In others, there may be lifestyle or behavioral factors that stress the LES and contribute to its failure. These factors include:

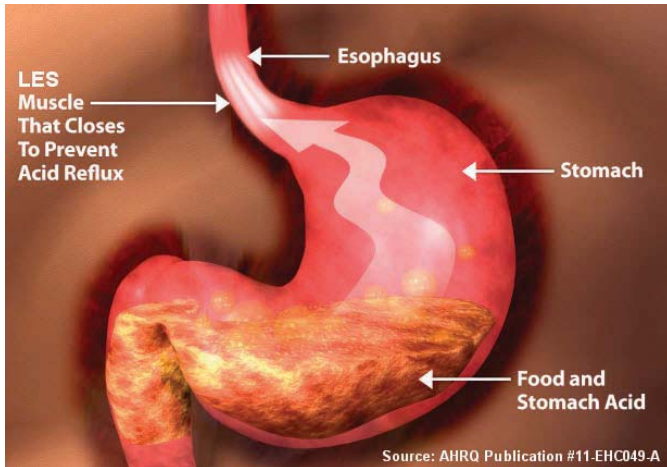
- obesity,
- smoking,
- alcohol use,
- a high fat diet, and
- consumption of carbonated beverages.

Additionally, a hiatal hernia can lead to GERD. Hiatal hernia results when the LES moves above the diaphragm, a sheet of muscles that separates the abdominal and chest cavities. When the LES moves into the chest, it is less able to prevent reflux. Finally, GERD symptoms can be compounded by defective clearance of acid and fluid from the lower (distal) esophagus due to esophageal damage or esophageal motility disorders.

Medical Management of GERD

Lifestyle Changes – The treatment of GERD begins with behavioral and lifestyle changes. Reduction of symptoms can be achieved in most individuals with several modifications. These include:

- weight loss,
- avoidance of carbonated beverages,
- abstinence from smoking,
- reducing alcohol and caffeine intake,
- avoiding “trigger” foods (spicy foods, citrus or acidic foods),
- maintaining a low fat diet,
- avoiding eating or drinking several hours before going to bed, and
- elevating the head of the bed at night.



Causes of GERD

GERD is caused by improper mechanical function of the lower esophageal sphincter (LES). The LES is a ring of muscle that surrounds the junction of the esophagus and the stomach and acts as a valve. When functioning properly, this valve opens when swallowing to allow passage of food from the esophagus into the stomach. The valve then closes and acts as a barrier to keep stomach contents from refluxing into the esophagus. In people with GERD, the LES does not properly close resulting in back-flow of gastric contents. It is the back-flow of gastric contents that cause the symptoms of GERD.



Medications – If symptoms are severe, or if symptoms persist despite lifestyle modifications, then medication should be considered. Acid reducing medications include proton pump inhibitors (PPIs) and histamine H₂-receptor blockers (H₂ blockers). It is important to understand, these medications do not stop reflux from occurring. However, they are often effective in reducing the amount of acid in the gastric fluid. In most people, acid reduction is enough to relieve or even eliminate symptoms of GERD. Medications are also very effective in treating complications of GERD such as esophagitis. In some people, however, long-term use of PPIs may be associated with an increased risk of osteoporosis and fractures of the hip, wrist, and spine. Although many of the most effective acid reducing medications are available over-the-counter, long-term use of greater than 2 weeks or failure of medications should be discussed with a physician.

Surgical Treatment of GERD

Surgical therapy is also an option for the treatment of GERD. The main indication for surgical therapy is failure of medical management when symptoms persist despite appropriate medical therapy. Another indication for antireflux surgery is personal preference. Some people do not want to take lifelong acid suppression medication or have too many side-effects from these medications and may want to consider antireflux surgery.

Required Testing Prior to Antireflux Surgery

Several tests are necessary to determine if a person is a good candidate for antireflux surgery. The purpose of these studies is to:

- identify objective evidence of reflux,
- correlate reflux with symptoms, and
- evaluate for other coexisting diseases that may be contributing to symptoms.

In general, all patients should have an *upper endoscopy*. Additional testing includes a 24-hour *pH test* with impedance, and an *esophageal manometry* study. Often, a patient will also have a contrast esophagram in the early stages of their evaluation.

Upper Endoscopy – An upper endoscopy or EGD involves placing a small camera through the mouth and into the upper gastrointestinal tract allowing evaluation of the esophagus, stomach, and first part of the small intestine (duodenum). This is generally done as an outpatient procedure under mild to moderate sedation. The purpose of endoscopy is to evaluate for reflux-related damage, to assess the integrity of the LES, and to identify any alternative or coexisting disease processes that may be contributing to symptoms. Long-term exposure of the esophagus to gastric acid can cause damage such as erosion (esophageal ulcers), inflammation (esophagitis), scarring (esophageal

stricture), and changes to the inner esophageal lining (Barrett's esophagus). During an endoscopy, potential abnormalities such as gastritis, peptic ulcers, polyps, nodules, and infections can also be assessed. Tissue samples (biopsies) of the esophagus, stomach and duodenum are often obtained during this procedure. Stomach tissue samples are often tested for an infection called *H. pylori*.

pH Test – A pH study involves a thin, soft silastic catheter inserted through a patient's nose and into the distal esophagus above the LES. Sensors on the tube detect and record acid reflux episodes. The device is also designed to record when a patient feels symptoms to determine if these symptoms correlate with reflux episodes. This test is conducted over a 24-hour period on an ambulatory patient who is off acid-suppression medications. During the test the individual is able to continue routine activities. One version of this test involves the attachment of an acid sensing chip on the lining of the lower esophagus. This is known as a Bravo probe and has the advantage of avoiding insertion of a tube through the patient's nose.

Many physicians are also utilizing the 24-hour esophageal impedance study for evaluation of reflux in certain patients. Esophageal impedance detects fluid reflux whether or not it is acidic. Both acid and non-acid reflux events are therefore measured. Individuals may have non-acid or weakly acid reflux, or continue to have symptoms despite high dose acid suppression and the impedance study can provide valuable information in these cases. One disadvantage to a Bravo study when compared to newer versions of the 24-hour pH study known as esophageal impedance is that only acid can be measured.

Manometry – Esophageal manometry measures the motor or contractile function of the LES and the esophagus. This test is mainly used to evaluate for any underlying esophageal motility disorders that may be contributing to a person's symptoms (such as achalasia).

Antireflux Surgery

Surgery for GERD is known as antireflux surgery and involves a procedure called a fundoplication. The goal of a fundoplication is to reinforce the LES to recreate the barrier that stops reflux from occurring. This is done by wrapping a portion of the stomach around the bottom of the esophagus in an effort to strengthen, augment, or recreate the LES valve. The most common type of fundoplication is a Nissen fundoplication in which the stomach is wrapped 360 degrees around the lower esophagus. There are also a variety of partial fundoplication techniques. As the name suggests, these techniques involve a wrap which does not go entirely around the esophagus. The Nissen fundoplication is almost always chosen to control GERD.



Antireflux operations today are most often performed using a minimally invasive surgical technique called laparoscopy. The technique utilizes a narrow tube-like camera and several long, thin operating instruments. In the operating room, the camera and instruments are inserted into the abdomen through several small (less than 1 cm or ½ inch) incisions on the abdominal wall. The operation is then performed within the abdominal cavity using camera magnification. The benefit of this type of minimally invasive technique is that it results in less pain, a shorter hospital stay, a faster return to work, smaller scars, and a lower risk of subsequent wound infections and hernias.

If the surgery cannot be safely completed using laparoscopy, the operation is converted to a traditional open procedure that involves an incision in the upper abdomen. The open technique is both safe and effective, but it sacrifices the aforementioned benefits of laparoscopy.

In either case, surgery should be performed by a specialist with appropriate training or high volume experience.

Recovery from Antireflux Surgery

After surgery, patients are generally admitted to the hospital for 1–3 days. This observation period is to ensure that the patient is free of nausea and vomiting, and able to tolerate drinking enough liquids to maintain hydration. Patients are generally discharged on a soft, pureed, or a liquid diet.

The dietary restrictions after surgery can vary, but in general, patients should expect to slowly advance to a solid diet over a 2–8 week period of time. The dietary restrictions are slowly lifted after several weeks and the patient progresses through a soft and/or post-Nissen diet. Many surgeons recommend that their patients only take crushed or liquid medications for several weeks after surgery.

Side Effects and Complications of Antireflux Surgery

Although antireflux surgery is considered both safe and effective, complications and undesirable side effects can occur. Below is a brief description, but these should be discussed with your surgeon before undergoing an operation.

After a fundoplication, some patients report difficulty belching or a sensation of abdominal bloating. This is rarely severe and generally resolves within the first 6 months after surgery. Some patients may also report an inability to vomit, and some patients also report increased flatulence and diarrhea.

Rarely, patients also report long-lasting dysphagia, or difficulty swallowing, after surgery. While some degree of dysphagia is common immediately following surgery due to swelling in the area of the operation, this usually resolves within several weeks after the surgery. Dysphagia is the reason most surgeons recommend a liquid or soft diet after surgery and advise patients to eat slowly, take small bites and chew food well. Persistent or long-standing dysphagia can usually be treated with endoscopic dilation and in rare cases a revision of the original operation may be required.

Complications can result from general anesthesia, bleeding, infection, and/or injury to nearby organs. Nearby organs include the stomach, esophagus, spleen, liver, vagus nerves, aorta, vena cava, diaphragm, lungs, and heart.

Overall, laparoscopic antireflux surgery when performed by an experienced surgeon is exceptionally safe and any significant operative complication is quite unusual.

Outcomes after Antireflux Surgery

The outcomes after laparoscopic antireflux surgery are generally excellent. In both short-term (1–5 years) and long-term studies (5–10 years), the vast majority of patients report effective symptom reduction, a high level of satisfaction, and an improved quality of life after having the surgery. Nearly all patients are taken off of reflux medication after surgery. The most telling factor is that patients have consistently reported that if they were to do things over, they would again make the decision to undergo antireflux surgery.

The most important factor in determining if a patient will experience an improvement or resolution of their GERD-attributed symptoms is to ensure with a great deal of certainty that these symptoms are actually from GERD. For this reason, a proper evaluation before the operation is imperative. For extra-esophageal symptoms such as cough and hoarseness, the many other conditions not related to GERD are possible. In many of these cases, appropriate testing and multidisciplinary evaluation with a surgeon, a gastroenterologist, an otolaryngologist (ear, nose, and throat specialist), and a pulmonologist (lung and respiratory specialist) is important in confirming the diagnosis and ruling out other potential causes.

Reflux in People who are Morbidly Obese

Obesity is a major risk factor for GERD. Weight loss has been demonstrated to consistently lead to an improvement in GERD-related symptoms in obese patients. Some morbidly obese

The most important factor in determining if a patient will experience an improvement or resolution of their GERD-attributed symptoms is to ensure with a great deal of certainty that these symptoms are actually from GERD.



patients with GERD who fail appropriate medical management may see a surgeon for a discussion about antireflux surgery. A laparoscopic Nissen fundoplication in a morbidly obese patient is quite difficult. Some data suggests that the failure rate of a laparoscopic Nissen in morbidly obese patients is increased compared to the non-obese. Bariatric (weight-loss) surgery has been demonstrated to be effective in controlling and curing GERD in some patients. Morbidly obese persons who have GERD that is uncontrolled by medical therapy and who meet the criteria for antireflux surgery should talk to their doctor about the option of bariatric surgery.

Emerging Therapies

Although the laparoscopic fundoplication is the current standard of surgical care, there is an evolving array of exciting new endoscopic, incisionless treatments for GERD under evaluation. The newest therapy is the transoral incisionless fundoplication (TIF). This is an incisionless fundoplication performed with an endoscope that is inserted through the mouth and into the stomach. Short-term results appear favorable in carefully selected patients; however, long-term studies have not yet been completed. Many emerging therapies for GERD are still being evaluated under experimental protocols and can only be performed at selected research centers.

Summary

GERD is the most common digestive disorder for which patients seek medical care. Approximately 10% of Americans suffer from daily symptoms or take medications to manage these symptoms on a daily basis. In most patients who do not tolerate medical therapy or in patients who have inadequate or incomplete relief of GERD symptoms from appropriate medical therapy, antireflux surgery – performed by experienced surgeons and in appropriately selected patients – is a safe and effective option.

Comparison of Benefits and Risks of GERD Treatments

Plain-language publications from the U.S. Department of Health and Human Services' Agency for Healthcare Research and Quality (AHRQ) compare the benefits and risks of treatments for gastroesophageal reflux disease (GERD). The publications are based on an updated evidence report.

GERD can be treated with medications or surgery. The report concluded that established drug-based therapy is effective. The report found that proton pump inhibitors (PPIs) tend to be more effective than H2 blockers. Comparisons between PPI types or dosages showed few consistent differences. The most common side effects cited for PPIs and H2 blockers were diarrhea, headache, and abdominal pain.

The AHRQ report concluded that a type of surgical treatment known as laparoscopic fundoplication is at least as effective as drug-based medical treatment for some patients, but also had a higher risk of serious side effects. The report also found that fundoplication surgery decreased, but did not always eliminate, the use of antireflux medications. The surgical treatment using an endoscopic variation of fundoplication also has been used to treat GERD, but AHRQ's analysis found there is not enough evidence to compare this type of surgery's effectiveness with other treatments.

The new publications – a summary for consumers and a companion publication for clinicians – are based on the findings of a comprehensive report updated for AHRQ's Effective Health Care Program by the Tufts Medical Center Evidence-based Practice Center. The report and the consumer and clinicians publications are available at www.effectivehealthcare.ahrq.gov.

The report, *Comparative Effectiveness of Management Strategies for Adults with Gastroesophageal Reflux Disease*, is an update to a 2005 report. The systematic review of 166 clinical studies published between January 2004 and August 2010 examined the comparative effectiveness, benefits, and adverse effects of treatments for GERD and investigated whether there are factors that influence or predict treatment effectiveness. It helps provide information that doctors and patients can use when considering a plan for treatment.

The review did not evaluate diagnostic approaches, treatment options for patients with symptoms resistant to treatments, or the effect of lifestyle modifications on GERD symptoms. It does not represent clinical recommendations or guidelines.

As with any chronic health disorder talk to your doctor about how your condition affects your life. Discuss your treatment goals and options. Understand treatment benefits and risks. Work in partnership with your doctor to help ensure the best results.



Tips on How to Get the Most from Your Doctor Visit

Going to the doctor can be stressful, especially if you are sick or worried. You may think that being a “good” patient means doing what your doctor tells you.

But the truth is, staying quiet is not a good idea. By asking questions and understanding your treatment options, you can share in making decisions with your doctor and receive the best possible care.

What is a treatment option, anyway?

A treatment option is a medicine or therapy to treat your problem. A treatment option may be a pill, a shot, exercise, or an operation (surgery). It could even be a combination of things.

The process of fully exploring your options starts with asking your doctor questions about your diagnosis or condition. The next step is a full discussion about the available treatments – including the concerns you have about options and which options might be best for you.

It may seem okay to follow the first treatment your doctor suggests and then wait to see if it works. But if you take the time to talk to your doctor about all your treatment options, you may find one that works better for you.

How can knowing your treatment options improve your life?

You might feel better – not only about your health problem but also about your treatment choice and your part in decision making. Telling your doctor what is important to you can help you find the best medical care and improve your quality of life.

Talking about treatment options may help you find:

- A treatment or medical test that could work best for you.
- A treatment with fewer side effects.
- A treatment that’s better for your budget.
- Better control over your health care.

Some people feel nervous about asking their doctor questions. Remember: You know more about your body, your health, and what’s important to you than anyone else. Don’t be afraid to speak up.

Health care can be confusing

Whether you are just starting treatment or your treatment is already underway, it is never too late to take an active role in your health care.

By talking with your doctor, nurses, and other people on your health care team, you can make sure you are not missing the best treatment for you.

Here are a few tips to help you better understand your treatment options:

Give your doctor as much information as you can – Don’t wait for your doctor to ask questions. Share everything – even information that might be embarrassing. This information can help your doctor make better recommendations.

Ask as many questions as you need to understand your diagnosis – If you do not ask questions, your doctor may think you understand everything you are being told. Write down your questions before your visit so you do not forget anything. Start by asking the most important ones and work your way down the list.

Make sure you really understand the information – Take notes, bring someone with you to the appointment, or ask how to get more information.

Remember to follow up – In some cases, you may need more information or care. Call your doctor’s office if:

- You have more questions.
- You feel worse.
- You have problems with your medicines.
- You have not gotten your test results.

You and your doctor can work together to find the best treatment for you.

Source: Agency for Healthcare Research and Quality, www.effectivehealthcare.abrq.gov/options/

Books of Interest

Here is a list of books, authored or edited by knowledgeable healthcare professionals, which provide trustworthy information about a variety of topics relating to gastrointestinal disorders and digestive health.

New in 2012

Title: *Managing Life with Incontinence*
Editors: Cheryle B. Gartley, Mary Radtke Klein, Christine Norton, and Anita Saltmarche
Publisher: The Simon Foundation (2012)
Pages: 232 (paperback)

Leakage, overactive bladder, fecal incontinence, stress incontinence... whatever you choose to call it, the fact is that life with incontinence can be challenging. This book provides guidance from leading experts about how to take control of daily life, even when living with incontinence. Chapters include information on treatments, communicating with friends, family, and health professionals, helpful resources, and overcoming stigma. Courageous stories from people who live, and thrive, with incontinence provide encouragement and inspiration. Written specifically for individuals who live day to day with bladder and/or bowel incontinence, the book also provides information useful for physicians and nurses who understand their patients' frustrations and wish to more fully comprehend the quality of life issues facing people with intractable incontinence. Available online at: www.simonfoundation.org.

New in 2012

Title: *The Ins and Outs of Poop*
Author: Thomas R. Duhamel, PhD
Publisher: Maret Publishing (2012)
Pages: 171 (paperback)

Functional constipation can persist for months or years. Treatment can be stressful for everyone involved, including healthcare providers. It is the most common problem seen in pediatric GI clinics. It can cause young children to soil their underwear (encopresis) without awareness that they have to use the toilet. It can cause discomfort and pain, and a deep sense of embarrassment in a child. But functional constipation goes away when treated correctly. This book provides a step by step guide to understanding, recognizing, and treating functional constipation, and a plan for parents and providers to work together as a

treatment team. Each step is explained in detail along with the tools needed for successful implementation. There are many stories written by parents describing specific aspects of their child's treatment. The illustrated book is written in a light-hearted fashion that emphasizes the good news that with comprehensive care, functional constipation can be dramatically improved.

The author is a clinical child psychologist who has collaborated with parents and pediatric care providers about functional constipation for over 30 years. Available online at Amazon.com.

New in 2012

Title: *IBS – Free at Last! (2nd Edition)*
Author: Patsy Catsos, M.S., R.D.
Publisher: Pond Cove Press (2012)
Pages: 171 (paperback)

This book describes an easy, step-by-step method for controlling IBS symptoms that may be caused by intolerance to certain carbohydrates (FODMAPS) in your diet. FODMAPs are problematic for those with IBS; they are poorly absorbed in the small intestine and rapidly fermented by bacteria in the gut. The book includes information to help you understand the link between certain foods and IBS symptoms. It includes menus, tips on shopping and reading labels, and strategies for including your favorite foods in your diet. The second edition offers new recipes and gives answers to the questions frequently asked by readers. Available online at Amazon.com.

Title: *Some Take Things to Heart, Others to Their Belly – Irritable Bowel Syndrome: What is it and how is it treated?*
Author: Ami D. Sperber, M.D.
Publisher: IFFGD (2011)
Format: Kindle Edition
File Size: 228 KB

If you, a friend, or a family member is suffering from IBS, this book is for you. As clinician long dedicated to helping people with functional disorders, Ami Sperber, M.D., provides a fresh and clear guide to help people understand

IBS and the diagnostic process. Individuals with IBS will find useful ways to self-manage and gain a greater sense of confidence. The approach is empowering, helping people improve chances for treatment success. The book contains clear and detailed explanations of treatment approaches. These range from diet to complementary and alternative medicine to medications and to combinations of therapies. For quick references or detailed explanations, this book provides it all.

Dr. Sperber is an internationally recognized physician and researcher. He has a lengthy history of contributing to the understanding of living with and treating IBS and related conditions. Forward by Douglas A. Drossman, M.D. Available online as an eBook at Amazon.com.

Title: *Living (Well!) with Gastroparesis – Answers, Advice, Tips & Recipes for a Healthier, Happier Life*
Author: Crystal Zaborowski Saltrelli, C.H.C.
Publisher: Sea Salt Publishing (2011)
Pages: 245 (paperback)

This book is a comprehensive and easy to follow guide to navigating life after a gastroparesis diagnosis. Certified Health Counselor and gastroparesis patient-advocate Crystal Saltrelli guides you through all aspects of managing gastroparesis, including self advocacy, appropriate medical treatment, complementary therapies, dietary modifications, nutrition and supplementation, supportive lifestyle practices, stress management, and coping skills. You'll also find practical tips and advice for socializing, travel, career, and relationships. The book concludes with 75 brand new GP-friendly recipes.

The author is a Certified Health Counselor specializing in gastroparesis management. Diagnosed in 2004 with gastroparesis, she provides a unique and useful perspective as someone with both personal and professional experience with the condition. Available online at Amazon.com.



Title: Nausea: Mechanisms and Management

Author: Robert M. Stern, Ph.D.; Kenneth L. Koch, M.D.; Paul L.R. Andrews, Ph.D.
Publisher: Oxford University Press (2011)
Pages: 462 (hardcover)

Nausea is a complex sensation associated with a number of GI disorders that results from the interaction of different factors. This is the first book to provide an in-depth explanation of what is known about nausea, along with latest research on its causes and treatment. The book addresses the mechanisms, management, and prevalence of nausea. It explores the roles of the central nervous system, autonomic nervous system, endocrine system, and gastric dysrhythmias. Treatment in several areas is described, including chronic nausea, diabetes, pregnancy, post-operative, cancer and its treatment, and provocative motion. A final chapter discusses future research, including novel treatment approaches involving the use of biofeedback, nutraceuticals, and adaptation. Written in collaboration by scientists from the three main approaches to studying and treating nausea – psychology, gastroenterology, and physiology. Aimed primarily at professionals. Available online at Amazon.com.

Title: Eating for Gastroparesis – Guidelines Tips & Recipes

Author: Crystal Zaborowski Saltreli, C.H.C.
Publisher: CreateSpace (2011)
Pages: 90 (paperback)

This user-friendly, easy to follow guide answers the most frequently asked questions about eating for gastroparesis, addresses common misconceptions, offers tips for symptom management, and provides 50 simple gastroparesis-friendly recipes. Following accepted dietary guidelines it offers detailed lists of ‘friendly’ foods, tips for enhancing nutrition and minimizing symptoms, and answers to common questions. The author is a Certified Health Counselor. Available online at Amazon.com.

Title: Functional Pain Syndromes: Presentation and Pathophysiology
Editors: Emeran A. Mayer, M.D. and M. Catherine Bushnell, Ph.D.
Publisher: IASP Press (2009)
Pages: 580 (paperback)

There is now a wealth of evidence that these “functional” disorders are associated with substantial neurobiological, physiological, and sometimes anatomical changes in the central nervous system. An outstanding group of experts in various fields provide a view of the current understanding and treatment strategies of some of the most prevalent types of chronic pain conditions, such as IBS, fibromyalgia, TMJD, vulvodynia, interstitial cystitis and others. This book is aimed primarily at professionals. Available through booksellers.

Title: Understanding the Irritable Gut: The Functional Gastrointestinal Disorders
Author: W. Grant Thompson, M.D.
Publisher: Degnon Associates (2008)
Pages: 240 (paperback)

The functional gastrointestinal (GI) disorders can perplex doctors and patients alike. This book seeks to demystify these disorders. Dr. Thompson explains with ease and clarity the nature, prevalence, and possible causes of these disorders. The information developed and assembled by the Rome Foundation to identify, classify, and treat these disorders is presented in an easy-to-read, nontechnical format. Available online at: www.theromefoundation.org.

Title: Noncardiac Chest Pain: A Growing Medical Problem

Editors: Ronnie Fass, M.D., Guy D. Eslick, Ph.D.
Publisher: Plural Publishing, Inc. (2007)
Pages: 188 (hardcover)

This book provides a comprehensive review of noncardiac chest pain provided by the current world authorities in the field on a variety of topics including epidemiology, cardiologist’s perspective, pathophysiology, non-esophageal causes, sensory testing, psychological disorders, diagnosis, use of proton pump inhibitors, brain imaging, economics, treatment, quality of life, prognosis, and future developments. The book is aimed primarily at clinicians and researchers. Available through booksellers.

Title: Controlling IBS the Drug-Free Way: A 10-Step Plan for Symptom Relief
Author: Jeffrey M. Lackner, Psy.D.
Publisher: STC Healthy Living (2007)
Pages: 256 (paperback)

The book offers a step-by-step self-management approach that anyone with IBS can easily follow to reduce symptoms without drugs or professional help. Also included are up-to-date overviews of medications and dietary strategies that readers can use to help with symptom control. Dr. Lackner is director of the Behavioral Medicine Clinic and Assistant Professor in the Department of Medicine at the State University of New York at Buffalo School of Medicine. Available through booksellers.

Title: Rome III: The Functional Gastrointestinal Disorders
Senior Editor: Douglas A. Drossman, M.D.
Publisher: Degnon Associates (2006)
Pages: 1,048 pages (hardcover)

Five years in the making, Rome III is designed for “one stop” learning for health professionals. Available online at: www.theromefoundation.org.

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.

The Procter & Gamble Company

NPS Pharmaceuticals, Inc

Medtronic, Inc.

Ironwood Pharmaceuticals, Inc.

Furiex Pharmaceuticals, Inc.

Forest Laboratories, Inc.

Treatment News

The U.S. FDA has Approved the Drug Linaclotide (Linzess) for the Treatment of Irritable Bowel Syndrome with Constipation and Chronic Constipation

On August 30, 2012, Ironwood Pharmaceuticals, Inc. and Forest Laboratories, Inc. announced that the U.S. Food and Drug Administration approved the New Drug Application (NDA) for linaclotide (Linzess®), a guanylate cyclase type-C (GC-C) agonist, to treat irritable bowel syndrome with constipation (IBS-C) and chronic constipation (CC) in adults aged 17 and older. Linaclotide is a drug used to relieve symptoms of abdominal pain, discomfort, bloating, and bowel symptoms in people who have IBS-C or CC. It has been shown to be safe and effective in trials. Linaclotide works by increasing the amount of fluid that flows into the bowel, allowing stool to pass more easily, and reducing visceral pain.

The safety and effectiveness of Linzess for the management of IBS-C were established in two, double-blind studies. A total of 1,604 patients were randomly assigned to take 290 micrograms of Linzess or a placebo for at least 12 weeks. Results showed Linzess was more effective in reducing the amount of abdominal pain and increasing the number of complete spontaneous bowel movements compared with placebo.

The safety and effectiveness of Linzess for the management of chronic idiopathic constipation also were established in two, double-blind studies. A total of 1,272 patients were randomly assigned to take Linzess at doses of 145 mcg or 290 mcg or a placebo for 12 weeks. Results from these studies showed patients taking Linzess experienced more complete spontaneous bowel movements than those taking the placebo. The 290 mcg dose is not approved for chronic constipation because studies indicated it was no more effective than the 145 mcg dose.

Linzess is approved with a Boxed Warning to alert patients and health care professionals that the drug should not be used in patients 16 years of age and younger. Linzess should not be used in patients with known or suspected mechanical gastrointestinal obstruction. The most common side effect reported in during the clinical studies was diarrhea.

Ironwood and Forest are co-producing linaclotide in the United States. Ironwood has out-licensed linaclotide to Almirall, S.A. for development in Europe; and to Astellas Pharma, Inc. for development in Japan, Indonesia, Korea, the Philippines, Taiwan, and Thailand.

European CHMP Recommends Approval for Linaclotide to Treat IBS-C

The European Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion recommending the marketing approval for linaclotide for the treatment of moderate to severe irritable bowel syndrome with constipation (IBS-C) in adults. The CHMP positive opinion is a recommendation to the European Commission (EC) and one of the final steps in the review of a marketing authorization application. It would be marketed under the brand name Constella, once approved.



Solesta is now Available in the U.S. to Treat Fecal Incontinence

In May 2011 the Food and Drug Administration (FDA) approved Solesta, a biocompatible tissue bulking agent, for the treatment of fecal incontinence in patients 18 years and older who have failed conservative therapy (e.g., diet, fiber therapy, anti-motility medications). 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.

Fecal 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.

The FDA based its approval on results from a clinical study of 206 patients. In the primary study, most patients received two treatments, consisting of four injections each, for a total of eight injections. After six months, more than half of the patients injected with Solesta experienced a 50 percent reduction in the number of fecal incontinence episodes. One-third of patients who received no Solesta in the study also experienced a similar reduction. Overall, a greater proportion of patients treated with Solesta experienced improvements, indicating the gel provides benefit.

Solesta is approved for use in patients ages 18 and up. 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. On December 20, 2011 Salix Pharmaceuticals, Ltd. acquired all of the outstanding stock of Oceana Therapeutics, Inc.

Rifaximin Shows Promise for Treatment on Non-Constipated IBS

Rifaximin is an antibiotic currently under investigation for the treatment of non-constipation irritable bowel syndrome (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 (watery or loose stools) after a 10–14 day course of treatment. It is only slightly absorbed in the gut and is generally tolerated well. Rifaximin is not yet approved by the FDA for the treatment of IBS.

FDA Approves new Clinical Trial Looking at Repeat Treatment with Rifaximin

On November 16, 2011 Salix Pharmaceuticals announced that the U.S. Food and Drug Administration (FDA) Gastrointestinal Drugs Advisory Committee supported the Salix/FDA developed proposed design of a clinical trial to evaluate the safety, efficacy and durability of response with repeat treatment cycles of Xifaxan (rifaximin) for irritable bowel syndrome with diarrhea (IBS). A multi-center, randomized, double-blind, placebo-controlled trial with IBS patients will look at the efficacy and safety of rifaximin on repeat treatment.

Patient enrollment is planned during the first quarter of 2012. About 24 months could be required for the company to complete the trial and secure an FDA decision regarding approval.

Results from two Phase 3 clinical trials involving 1,260 non-constipated male and female patients with irritable bowel syndrome were reported in the January 6, 2011 issue of the *New England Journal of Medicine* (NEJM) showing adequate relief of IBS symptoms, bloating, abdominal pain, and loose or watery stools.

Results from the multiple center studies indicated that 550mg rifaximin, taken orally 3 times a day for 14 days, achieved adequate relief of global IBS symptoms (primary endpoint) and adequate relief of IBS-related bloating (key secondary endpoint) in a significantly greater proportion of patients, compared with placebo, during the primary evaluation period (first 4 weeks following treatment) as well as during the entire study period (10 weeks following treatment). The statistically significant weekly findings in the primary endpoint and key secondary endpoint noted above were supported by daily findings in the secondary endpoints of global IBS symptoms, bloating, stool consistency and abdominal pain and discomfort. Additionally, the NEJM publication includes results of an analysis of a composite endpoint of abdominal pain or discomfort and loose or watery stools as outlined in the March 2010 draft FDA Guidance for Industry relating to the clinical evaluation of products for treatment of IBS.

The safety profile of rifaximin was similar to that of placebo.

Rifaximin is a gut-selective antibiotic with negligible systemic absorption and broad-spectrum activity in vitro against both gram-positive and gram-negative pathogens. It is currently approved by the FDA for treatment of travelers' diarrhea (under the trade name of Xifaxan®), but at lower doses and shorter duration of therapy than being studied in IBS. It is not yet approved by the FDA for the treatment of IBS.

Amitiza Study Looks at Long-Term Safety

Amitiza (lubiprostone) is a prescription drug used to relieve stomach pain, bloating, and straining and produce softer and more frequent bowel movements in men and women who have chronic idiopathic (functional) constipation, and to treat irritable bowel syndrome with constipation (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.

A study of Amitiza published in the March 2012 issue of the journal *Alimentary Pharmacology & Therapeutics* looked at the long-term safety, tolerability, and patient outcomes in people with irritable bowel syndrome with constipation (IBS-C). The researchers concluded that in patients with IBS-C, lubiprostone 8 mcg twice daily was found to be safe and well tolerated over 9–13 months of treatment. The study provides preliminary evidence for the safety of lubiprostone in the long-term treatment of IBS-C.

The study was funded in part by Sucampo Pharma Americas, Inc., Bethesda, MD and in part by Takeda Pharmaceuticals USA, Deerfield, IL.

Amitiza Approved in U.K to treat Chronic Constipation

The U.K. Medicines and Healthcare Products Regulatory Agency has approved lubiprostone (Amitiza) for the treatment of chronic idiopathic constipation (CIC) and associated symptoms in adults, when response to diet and other non-pharmacological measures are inappropriate.

Lubiprostone Results Positive in Treating Opioid-Induced Bowel Dysfunction

The U.S. Food and Drug Administration (FDA) has given priority review to an additional indication for lubiprostone for the treatment of opioid-induced constipation (OIC) in patients with

chronic, non-cancer pain. FDA's decision is expected by late January 2013.

Lubiprostone 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.

The phase 3, randomized, placebo-controlled, double-blinded trial looked at the efficacy and safety of lubiprostone in patients with opioid-induced bowel dysfunction. The primary endpoint was the overall spontaneous bowel movement response rate. Over a 12 week period, the response rate for 219 lubiprostone-treated patients was 26.9% versus 18.6% for 220 placebo-treated patients.

The trial included patients in the U.S. and Europe who continued opioid therapy throughout the study.

No drug-related serious adverse events were reported for patients taking lubiprostone. The most common treatment-related adverse events (experienced by 5–10% of patients) were diarrhea, nausea, and abdominal pain.

Lubiprostone currently is available under the name Amitiza to treat chronic idiopathic (functional) constipation and irritable bowel syndrome with constipation.

The New Drug Application for Gattex to Treat Short Bowel Syndrome is under Review by the U.S. Food and Drug Administration (FDA)

Gattex (teduglutide) is a drug currently under investigation by NPS Pharmaceuticals, Inc. for the treatment of short bowel syndrome (SBS). Short bowel syndrome 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, and cannot absorb enough water, vitamins, and other nutrients from food. They may then need to use parenteral nutrition (PN) and intravenous (IV) fluids, the slow infusion of a solution of nutrients and fluids into a vein.

Gattex 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 PN and IV fluid volume in adult subjects with short bowel syndrome.

On October 16, 2012, the FDA's Gastrointestinal Drugs Advisory Committee voted unanimously to recommend approval of Gattex for adults with SBS. The drug is currently under review by the FDA, which is expected to make a final decision on the drug by the end of this year.

Gattex is a novel peptide involved in gastrointestinal regeneration and repair (recombinant analog of human glucagon-like peptide 2). NPS Pharmaceuticals is a specialty pharmaceutical company developing orphan therapeutics for rare gastrointestinal and endocrine disorders.

The company's SBS clinical development program represents the largest and most comprehensive to date. The information in the NDA is derived from fourteen completed and one ongoing clinical study. A total of 566 subjects have been treated with teduglutide. Of the 566 subjects treated with teduglutide, 299 subjects were treated in the clinical pharmacology studies, 94 subjects in Crohn's Disease studies, and 173 subjects in the SBS efficacy and safety studies. Of the 566 Gattex-treated subjects, 97 SBS subjects had at least 12 months of exposure to Gattex. Across the company's Phase 3 studies, a total of 15 patients were able to achieve independence from PN/IV. Side effects include abdominal pain,



Professional Announcements

Save the Date – IFFGD Professional Symposium

IFFGD will host the **10th International Symposium on Functional Gastrointestinal Disorders on April 12–14, 2013** at the Pfister Hotel, Milwaukee, WI. This CME accredited meeting is jointly sponsored by the University of Wisconsin School of Medicine and Public Health, Office of Continuing Professional Development in Medicine and Public Health, Madison, WI and the International Foundation for Functional Gastrointestinal Disorders (IFFGD).

This biennial meeting draws an international audience and addresses issues of interest to multiple health care disciplines, from basic science to clinical care. Consider attending if you are a gastroenterologist, pediatrician, primary care physician, physiologist, basic scientist, epidemiologist, mental health professional, nurse clinician, physician assistant, trainee, or involved in other allied health fields.

- Learn about advances in the pathophysiology of the functional gastrointestinal and motility disorders.
- Develop clinical skills in the diagnosis and care of patients with functional GI disorders.
- Network and share information and experiences with other conference participants.

Learn more about this unique biennial meeting and the many reasons to attend. View a video about the Symposium at: www.iffgd.org/site/news-events/events/professional-symposia.

For further information, contact:

Elisabeth Vink, IFFGD
Phone: 414-964-1799
email: symposium@iffgd.org
Terese Bailey, OCPD in Medicine and Public Health
Phone: 608-240-2141
email: tmbailey@ocpd.wisc.edu

Or go to the IFFGD web page at www.iffgd.org/symposium.



Scan this code with your smart phone for more information.

Asian Pacific Digestive Week 2012

When: December 5–8, 2012
Location: Bangkok, Thailand
Email: secretariat@apdw2012.org
Website: www.apdw2012.org

Canadian Digestive Diseases Week 2013

When: March 1–4, 2013
Location: Victoria, British Columbia, Canada
Email: CDDW@cag-acg.org
Website: www.cag-acg.org

Digestive Disease Week (DDW) 2013

When: May 18–21, 2013
Location: Orlando, Florida, USA
Email: ddwadmin@gastro.org
Website: www.ddw.org

American Neurogastroenterology and Motility Society (ANMS) Annual Meeting 2013

When: September 20–22, 2013
Location: Huntington Beach, California, USA
Abstract Deadline: March 29, 2013
Email: admin@motilitysociety.org
Website: www.motilitysociety.org

World Congress of Gastroenterology (Gastro 2013)

When: September 21–24, 2013
Location: Shanghai, China
Email: congress@gastro2013.org
Website: www.gastro2013.org



Community News



The Digestive Health Alliance (DHA) is the grassroots arm of IFFGD

Looking Ahead to the 113th Congress

The 112th Congress is coming to a close and the 113th Congress will begin on January 3, 2013. A “new” Congress begins every two years in January, following November elections. In addition to swearing in new Representatives and Senators, a new Congress will start over with new legislation to consider. If a bill has not been acted on before the end of a Congress, it can be reintroduced in the new Congress (often with a new number) and the legislative process will be started again.

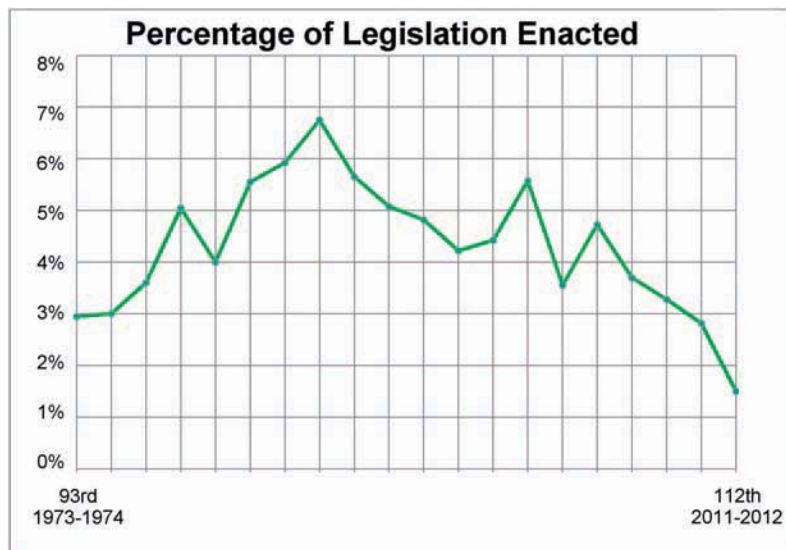


Table 1

The Functional Gastrointestinal and Motility Disorders Research Enhancement Act is one of many bills that did not become law during the 112th Congress. But that is not unusual. Members of Congress introduce thousands of bills each year. Less than 10% of the bills introduced become law during their first Congress, so it is important to support a proposal through the entire process. See Table 1 to see the percentage of bills introduced that became law each Congress, going back to 1973.

The Functional Gastrointestinal and Motility Disorders Research Enhancement Act of 2011 was introduced by Representative F. James Sensenbrenner, Jr. (WI-5) in the House of Representatives in June 2011 with bill number H.R. 2239. It has gained bipartisan support, with cosponsors including Representatives James Moran (VA-8), Peter Welch (VT), Elton Gallegly (CA-24), Jesse Jackson, Jr. (IL-2), Tammy Baldwin (WI-2), Maurice Hinchey (NY-22), Gwen Moore (WI-4), Nan Hayworth, M.D. (NY-19), Ed Perlmutter (CO-7), David Price (NC-4), Mazie Hirono (HI-2), Ron Kind (WI-3), Dan Boren (OK-2), Bill Posey (FL-15), Eijajah Cummings (MD-7), and Susan Davis (CA-53).

In the 16 months since its introduction, nearly 1,000 digestive health advocates have reached out to their Representative in support of *The Functional Gastrointestinal and Motility Disorders Research Enhancement Act*. These advocates represent many different disorders and they come from 48 states, plus the District of Columbia. By speaking out, they help raise critical awareness about functional GI and motility disorders and the devastating effects they can have on the patients and families who live with them. Thank you to everyone who has taken action so far!

The Functional Gastrointestinal and Motility Disorders Research Enhancement Act will be reintroduced in the 113th Congress and it needs your continued support. We will keep you updated about what you can do to support The Functional Gastrointestinal and Motility Disorders Research Enhancement Act as we move forward. With continued action from digestive health advocates, we will see that this bill is passed!

Did you know?

Following the 2010 census, the boundaries of many congressional districts will change with the 113th Congress. Find your district and Representative any time by entering your zip code at www.iffgd.org/action.



Community News



Awareness Walk for Gastroparesis

The first annual Awareness Walk for Gastroparesis (GP) in Bellingham, WA took place Saturday, September 8, 2012. The walk was a great success raising nearly \$3,000! Proceeds went to the Digestive Health Alliance to fund research aimed at improving and saving lives of people suffering from gastroparesis.

Thank you to all those that helped sponsor the walk: Advanced Medical Massage, CarrDorsh Family Dental, GoMacro, Hoagland Pharmacy, Journey with Gastroparesis, and RoibaGear.

Many thanks to Stephanie Torres for organizing this fundraiser. Here is how Stephanie described the event:



"We began at the farmer's market at noon, along the scenic interurban trail between the Bellingham Farmers Market and Boulevard Park. Participants walked down the interurban trail along the bay towards Boulevard Park, wrapped around Woods Coffee and came back to the market. A booth was set up for registration and important information about GP. T-shirts were available, along with a selection of exciting silent auction items.

Weather could not have been more perfect, sunny, 80 degrees and no wind. So thankful for all the volunteers and their hard work, this could not have been possible without them. We had several visitors up from Seattle area and met many locals who are dealing with similar issues and learned so much."

Want to get involved? You can create your own fundraiser, tell us your event idea, or donate. Go to our website at www.dha.org or send us an email at dha@iffgd.org.



Community News

IFFGD Provides Written Public Testimony To FDA

IFFGD presented the following views to the Department of Health and Human Services, Food and Drug Administration (FDA) in connection with an October 16, 2012 meeting of the Gastrointestinal Drugs Advisory Committee to consider the new drug application (NDA) 203441 by NPS Pharmaceuticals for the drug with the proposed trade name Gattex (teduglutide) for the treatment of adult patients with short bowel syndrome (SBS). Docket No. FDA-2012-N-0001.

On behalf of the International Foundation for Functional Gastrointestinal Disorders (IFFGD), I thank the Food and Drug Administration (FDA) for its work to evaluate treatments for conditions that affect the public. IFFGD is a 501(c)(3) nonprofit education and research organization dedicated to improving the understanding of functional gastrointestinal and motility disorders.

I am writing to you to offer comments regarding the October 16, 2012 meeting of the Gastrointestinal Drugs Advisory Committee. At this meeting, the Advisory Committee will consider the new drug application (NDA) 203441 by NPS Pharmaceuticals for the drug with the proposed trade name Gattex (teduglutide) for the treatment of adult patients with short bowel syndrome (SBS).

Short bowel syndrome is a complex condition characterized by the loss of absorptive capacity of the small intestine. It can occur in people at any age. The cause can be congenital, or acquired due to a variety of reasons. In some the condition can be life-threatening.

People face numerous difficulties as a result of having SBS. In addition to managing multiple symptoms, extraordinary measures must be taken to ensure that individual fluid and nutrient requirements are met. These measures include high levels of doctor-patient communication and patient/care-giver education, frequent healthcare utilization, carefully monitored diets, and often the need to use parenteral nutrition and intravenous fluids. The long-term use of parenteral support increases risks of infection and other complications, which themselves can be life-threatening, and is associated with numerous quality of life issues such as loss of sleep, mobility, and social interactions.

Treatment options over the long course of SBS are burdensome on patients, care-providers, and healthcare providers. Treatments are aimed primarily at maintaining adequate nutritional status and preventing complications. However, complications can arise not only as a result of the underlying condition, but also in connection with treatments such as parenteral infusions.

New treatment options are needed to help people with short bowel syndrome more effectively manage their condition, maintain required nutritional status, and reduce use of parenteral support for those who rely on it. If Gattex (teduglutide) is found to be a safe and effective therapy, it would be a significant step forward for patients with short bowel syndrome.

Thank you for your consideration of our comments.

– William F. Norton, IFFGD



Q & A – What do you Say?

Here is a recent posting and responses on our www.facebook.com/IFFGD page. We invite you to join the conversation.

I would like to see a cure for _____ because _____.

- IBS because I want my life back!
- Fructose intolerance because my daughter was diagnosed with it at 5 years old
- Gastroparesis because two years later, I really can't believe I will have this forever! Sick and tired of being sick and tired!
- ALL functional GI disorders because I too want my life back!
- All GI disorders because no one should be afraid of food and how it will affect them day after day.
- A cure for C Diff, because it destroys lives. And apparently there is one on the horizon! Poop transplants. REALLY!
- Colonic inertia because the only thing left for me is removal of the colon, and I'm not quite ready for that.
- All gastro syndromes because they put life on pause!
- All GI disorders. Cause it takes over your life!
- Gastroparesis...because I want my life back.
- Hirschsprung's disease because little babies shouldn't have to suffer through surgery or be dilated for months on end. The baby moments should be remembered as fun!
- Chronic intestinal pseudo-obstruction...because it stole the love of my life when she was 23. I miss her everyday and I wish we'd had the opportunity to live a long, happy life together.
- All illness so we can all be healthy and enjoy life.
- IBS because I'm tired of all that comes with it!
- Autism because 1 in 88 children are touched by it including my Grandson.
- All diseases/illnesses because no one should have to go through that.
- IBS-D cause I've suffered from it for 21 yrs.
- IBS...and diabetes.
- All GI disorders because it consumes children from birth onward and completely runs their lives forever.
- All GI disorders (especially) gastritis.
- Food protein induced enterocolitis because it is an ugly allergy that affects infants and toddlers.
- Hirschsprung's disease because I'm tired of watching my son have to deal with it.
- I want a cure for functional dyspepsia, because it sucks to have nausea all the time.
- Lupus because it does very serious damage to many people's bodies that I can't explain on here.
- Cyclic vomiting syndrome because my son deserves to enjoy his life rather than suffer almost every day.
- "Idiopathic" gastroparesis, because it totally disrupts sufferers' lives.
- IBS because I am tired of being in pain.

Community News

Some Digestive Disorders Just Won't Go Away Without Your Help



Donate to support research and say goodbye to chronic digestive disorders.

About 1 in 4 children and adults is affected by a chronic digestive disorder.

Your support enables research that improves the lives of millions with these conditions.

Your tax deductible donation changes lives. You can join in the search for cures.

Donate securely online at:
www.iffgd.org/donate

IFFGD/DHA
700 W. Virginia St., #201
Milwaukee, WI 53204



Here are some chronic, long-term digestive disorders that often just won't go away:

Chronic heartburn
Reflux disease or GERD
Swallowing disorders
Dyspepsia
Gastroparesis
Cyclic vomiting syndrome (CVS)
Chronic abdominal pain
Hirschsprung's disease
Intestinal pseudo-obstruction
Short bowel syndrome
Bowel incontinence
Irritable bowel syndrome (IBS)
Chronic bowel disorders

Functional gastrointestinal/motility disorders are among the leading causes of doctor visits, hospitalizations, and disability each year. These digestive conditions span a wide spectrum of disorders that affect the GI tract, including the esophagus, stomach, and intestines.

Advances in medicine largely depend on the gathering of new knowledge. IFFGD recently called for nominations for Research Awards in six categories. Applications are reviewed by our independent Selection Committee.

The IFFGD Research Awards will be presented in April 2013. *Your support makes these awards possible.*

Opinions expressed by authors are their own and not necessarily those of the International Foundation for Functional Gastrointestinal Disorders (IFFGD). IFFGD does not guarantee or endorse any specific product nor any claim made by an author and disclaims all liability relating thereto.

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.

For permission to reproduce any portion of this publication, contact IFFGD.

Editorial Staff:

Editor: William Norton
Assistant: Abigail French
Assistant: Susan Schneck

Associate Editors:

Ronnie Fass, M.D.
Douglas Drossman, M.D.
Paul Hyman, M.D.

Editorial Board:

Adil E. Bharucha, M.D.
Leslie Bonci, M.P.H., R.D.
Lin Chang, M.D.
William Chey, M.D.
David Fleisher, M.D.
Tony Lembo, M.D.
Hayat Mousa, M.D.
Ami Sperber, M.D.
J. Patrick Waring, M.D.

This issue of *Digestive Health Matters* is sponsored, in part, by Forest Laboratories, Inc., Ironwood Pharmaceuticals, Inc., Salix Pharmaceuticals, Inc., and the members of IFFGD. We are grateful for their continued support of IFFGD.

 **Forest Laboratories, Inc.**


Ironwood


Salix
PHARMACEUTICALS, INC.
ADVANCING TREATMENT IN GASTROENTEROLOGY

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**

700 W. Virginia St., #201
Milwaukee, WI 53204
Toll-free (U.S.): 888-964-2001
Business: 414-964-1799
Fax: 414-964-7176
E-mail: iffgd@iffgd.org
www.iffgd.org
www.aboutconstipation.org
www.abouttibs.org
www.aboutincontinence.org
www.aboutgerd.org
www.aboutgimotility.org
www.aboutkidsgi.org
www.giresearch.org
www.dha.org