



International Foundation for  
Functional Gastrointestinal Disorders

**IFFGD**

*Information. Assistance. Support.*

# Digestive Health Matters

Participate in your own health care | Vol. 21, No. 1, © 2012 IFFGD

## **3 April is IBS Awareness Month**

## **4 What is IBS?**

## **6 Research News You Can Use**

FDA Approves New Treatment for GERD

FDA Issues PPI Safety Alert

Understanding the Disease Process in Gastroparesis

Bloating is an Important Symptom in Gastroparesis

New Discoveries about Gut Bacteria in Children with IBS

## **8 Be an Active Member of Your Health Care Team**

## **10 Books of Interest**

## **12 Industry Treatment News**

## **16 Professional Announcements**

Qualified Investigators Sought for Phase 3 Trial

ANMS Postgraduate Course

Joint International Neurogastroenterology and Motility Meeting

IFFGD Seeking Applications for 2013 Research Awards

Save the Date – 10th International Symposium on FGIDs

## **18 Community News**

Courageous Story

Take Part in Digestive Health Alliance Advocacy Day 2012

Budget Cuts Threaten Medical Research

Make the Functional GI & Motility Disorders Research Enhancement Act Law

Raising Awareness – IBS Public Service Announcement

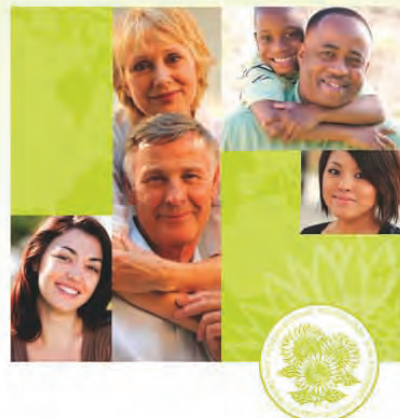
You can Help Find Cures for Children

Personal Advocacy

*A Little Knowledge can Make a Big Difference*

*www.iffgd.org*

# APRIL IS IBS AWARENESS MONTH



If you have IBS, you're not alone.

It's not always easy to talk about. Yet, irritable bowel syndrome, or IBS, affects over 30 million people in the U.S. — males and females, young and old. If you have chronic and recurrent abdominal pain and bowel problems... If your daily schedule is often ruled by intestinal discomfort... get help. IBS is a complex condition but there are ways to help manage it. Talk to your doctor.

## Don't suffer in silence.

The International Foundation for Functional Gastrointestinal Disorders (IFFGD) is a nonprofit organization that offers information and support. We answer questions and provide information that you need to help regain control of your life.

**Contact IFFGD to learn more or help in the search for a cure.**

Toll-free (U.S.): 888-964-2001 — Email: [iffgd@iffgd.org](mailto:iffgd@iffgd.org) — Web: [www.aboutIBS.org](http://www.aboutIBS.org)  
[www.facebook.com/IFFGD](http://www.facebook.com/IFFGD)



International Foundation for  
Functional Gastrointestinal Disorders

**IFFGD**

700 W. Virginia St. Ste 201, Milwaukee, WI 53204



# April is IBS Awareness Month

April 2012 Media Release by IFFGD

## Calling Attention to a Serious Issue for Returning Veterans

High numbers of veterans returning from the Gulf War regions of Iraq and Afghanistan are experiencing symptoms of irritable bowel syndrome (IBS) and other functional gastrointestinal (GI) disorders.

This prompted the Department of Veterans Affairs (VA) last August to implement a new rule for the purposes of assessing disability benefits. Veterans deployed during the Gulf War who now suffer with a functional GI disorder are presumed to have developed the condition as a result of their military service. IFFGD (the International Foundation for Functional Gastrointestinal Disorders) is advocating for more and better ways to support these veterans.

“Otherwise healthy individuals are experiencing digestive issues that can be debilitating. These issues began during deployment and then continue long after they have returned home,” said Nancy Norton, president and founder of IFFGD.

“These conditions disrupt veterans’ regular daily activities and, sometimes, their efforts to return to a normal life.”

No single cause of IBS and other functional GI disorders has been identified. “Long-term or repeated exposure to high levels of stress can cause physical changes in the brain and the intestines,” explained Brennan Spiegel, a medical advisor to IFFGD and Associate Professor of Medicine at the VA Greater Los Angeles Health Care System, Division of Digestive Diseases, UCLA School of Medicine and Division of Gastroenterology.

“Military personnel also often are exposed to gastrointestinal infections from food or water and other environmental factors,” Dr. Spiegel said. “These combined factors could trigger the long-term debilitating GI symptoms we are seeing in returning veterans.”

IFFGD is supporting veterans who have been affected by IBS and other functional GI disorders through an awareness and advocacy campaign. This effort aims to educate and promote improved care and increased research. Veterans are helping advocate for more support. Their stories illustrate the need for more information about IBS and functional GI disorders and improved care for those afflicted.

## Goals include:

- Increasing awareness and education among care providers to encourage prompt, accurate diagnoses and treatments.
- Making more facilities available to treat soldiers with these disorders.
- Increasing research that will help better understand these conditions and their relationship to military service.

IBS occurs in approximately 10 to 15 percent of the general population. It is characterized by a group of chronic symptoms that include abdominal pain along with constipation and/or diarrhea. Other intestinal symptoms may include bloating or nausea. While almost everyone suffers from intestinal symptoms from time to time, IBS symptoms return again and again, often without warning. There are no cures for IBS, but some treatments can ease its symptoms. A diagnosis by a healthcare professional and education about the disorder are important first steps.

## Quick Questions and Answers about IBS

### How do I know if I have IBS?

IBS can be diagnosed by a doctor, mainly based on a known pattern of symptoms. There is no test for IBS. Sometimes tests are done to make sure something else isn't causing the symptoms.

### Does IBS lead to colitis or cancer?

No, having IBS does not put you any more at risk than anyone else for getting colitis or cancer. People with IBS have no greater need of preventive checkups than other people.

### Does diet cause IBS?

No, diet does not cause IBS. But sometimes eating can make symptoms worse. In IBS the bowel may over-react. Just the act of eating, and not a specific food, can sometimes bring on or worsen symptoms. It is important to eat a healthy diet. And it usually helps to eat less of foods that would stimulate the bowel in anyone – like fried foods or high fat foods. Keeping a daily diary for a few weeks – like the one we have posted at [www.aboutIBS.org/diary](http://www.aboutIBS.org/diary) – can help sort out what foods may be a problem for you.

### What's the cure for IBS?

There is no cure for IBS, yet. It's a long-term condition. But there are treatments to help control the symptoms or ways to manage the condition.



# What is IBS?

By: Ami D. Sperber, M.D., M.P.H.S., Emeritus Professor of Medicine, Faculty of Health Sciences, Ben-Gurion University of the Negev, Beer-Sheva, Israel; Department of Gastroenterology, Tel-Aviv Medical Center, Tel-Aviv, Israel

This article is adapted from the Introduction of the eBook, *Some Take Things to Heart, Others to their Belly – Irritable Bowel Syndrome: What is it and how is it treated?* Published by IFFGD, the eBook by Ami D. Sperber, M.D. is available on Amazon.com. You can view it on your Kindle, or on the free Kindle reader, which you can upload on your computer or tablet. While not published in print, contact IFFGD and we can arrange to send you a spiral bound copy.

## Personal story – A.B, a 19-year-old woman relates:

*For as long as I can remember I've had stomach aches. I remember how, when my girl friends wished for a Barbie doll over their birthday candles, I wished that my belly could be traded in for a better one – that someone would do some kind of operation, remove my pain-filled belly and exchange it for a new one. A childish and innocent wish, I admit, but as a child I was sure it could be done and I still make the same wish year in and year out.*

*People who don't have IBS think it's a simple bellyache that will go away in a few minutes. They don't understand that we (I) have this severe pain, every day for hours... a pain that I cannot actually explain in words, pain that makes me want to tear my belly out, a pain that makes me lose concentration, no matter how much I try to ignore or repress it, it is always there. I'll tell you a true story about my life. As a young woman I like to go out, to meet new people... like anybody else. But most of the time "this" belly forces me to change my plans. Suddenly it hurts before I'm about to go out. Or even worse, it starts to hurt in the middle of an important date. If you haven't caught on yet, when I say "hurts," I don't mean just any pain. It's pain that causes you to lose control, to forget where you are and who you are... and just to concentrate on the pain. And believe me, when the person sitting across from me, who doesn't know me well, sees me begin to double up with pain... he's no longer interested in becoming a part of my life. He'd rather not enter that sick bed. It's so embarrassing and discouraging!*

*So that's that. There are a lot of limitations and the pain is horrible. But it's my life and I won't let any bellyache no matter how strong, ruin it or remove the smile from my face. Because, in my opinion, smiling is the best remedy for the pain!*

*This book is dedicated to A.B. and others like her who have IBS or a similar disorder. In it I will explain the nature of the disorder and how it is diagnosed and treated.*

## What is IBS?

IBS is the most common of the functional disorders of the digestive tract. It is characterized by chronic abdominal pain and irregular bowel movements. The cause of the symptoms is not found on routine testing. In other words nothing is found to be wrong in the tests.

“...a pain that I cannot actually explain in words, pain that makes me want to tear my belly out...”

## My Acquaintance with IBS Patients

Many times IBS patients are told by doctors that “nothing is wrong” with them. Over the years I have met and treated many IBS patients. It's hard to describe how much people suffer who have “nothing wrong with them,” or how severely their quality of life is affected. I have met people who hardly ever leave their home because they're afraid of an “accident,” because their stomach is bloated, or because they're afraid that they'll ruin their friends' or partner's fun.

I have met grandparents who do not travel to see their grandchildren because they are too afraid to take public transportation, men and women who go out to eat and do not touch the food in order not to make a scene, people who do not travel because of the need to wait in line for and use public restrooms, and others who have traveled, only to leave their families and return home ahead of time. I have come to know men and women who avoid meeting members of the opposite sex because, “Who would want to date someone with problems like mine?” People have told me how they prepare maps of all available restrooms along a travel route. Many of them can rate the restrooms on cleanliness, availability of soap, paper, seat covers, etc. I have spoken to patients who decide where to shop, not on the basis of the quality of the produce or its price, but on the availability and maintenance of restrooms.

There are many other IBS sufferers whom we doctors have not met or treated. Some are too embarrassed and others do not believe that we can help them. However, I also know many patients who feel much better as a result of our care.

My belly also aches sometimes. At those moments I think of my patients. My belly hurts me very infrequently, but when it does I often become tense. I find it difficult to concentrate and cannot enjoy what I'm doing. In contrast, a large percentage of the patients I see suffer from abdominal pain many hours of the day, most days of the year. How can anyone get used to that? Can one “learn to live with it,” as many doctors recommend?

## Some Basic Concepts

There are several basic concepts that can help us to gain insight into the complexity of functional disorders like IBS. In this introductory chapter I will begin with a couple of terms:

1. organic vs. functional disease, and
2. acute vs. chronic disease.

A third concept that will be presented in this chapter is quality of life. Understanding these concepts will serve as the foundation for understanding the rest of the book.

## “Organic” vs. “Functional” Diseases

In medicine a distinction is often made between “organic” and “functional” diseases. Organic diseases have objective findings, such as blood tests, x-rays, or invasive procedures that yield pathological results (in other words results that indicate the presence of disease). In the digestive tract, for example, such a result could be an ulcer, inflammation of the small intestine, or cancer of the large intestine. Patients with organic diseases have “proof” that it’s not all in their head.

This can be contrasted with functional diseases, which, while involving organic processes, stem from a problem with the functioning of the system and not its structure. For example, in the digestive tract the intestines may not move in an appropriately coordinated manner (motility problem), leading to irregular bowel movements, or there may be a reduced threshold for pain, causing chronic abdominal pain. It’s important to understand that routine clinical tests do not check for these functional problems. Thus, all the tests are normal and the patient may be seen as suffering from a psychological problem.

In modern medicine the burden of disease is measured not only by objective findings, but also by its impact on the patient’s life.

## “Acute” vs. “Chronic” Diseases

Functional disorders, like many other diseases, are chronic in nature. In medicine we often distinguish between acute and chronic disease. The concept “acute” does not refer to the severity of the disease, but to its duration. Acute diseases last for weeks, at the most, until they pass of their own accord or are totally resolved by medical therapy. In contrast, chronic diseases persist and become a part of the person’s life. There are many examples of chronic diseases. Diseases of the joints, diabetes, hypertension, and inflammatory bowel disease are some examples. These diseases can be treated and some have a natural course of waxing and waning symptoms, but there is no cure for any of them. The functional disorders of the digestive tract, such as IBS, belong to this type of chronic disease.

## Quality of Life of IBS Patients

In modern medicine the burden of disease is measured not only by objective findings, but also by its impact on the patient’s life. This impact is measured primarily in terms of quality of life, a very complex concept. Some of the elements that comprise quality of life are social or psychological rather than biological. Doctors can point to situations in which patients who are considered to have a more “serious” disease on the basis of medical indicators function better in all ways (work, family, etc.) than patients who have a “milder” disease but do not seem to be able to function well at all. How can this apparent paradox be explained? The “bio-psycho-social” model of medicine, which will be explained in this book, comes to our aid in this respect. This model attempts to encompass all the factors that affect illness and health, not only the physical ones, and to look at their impact on syndromes such as IBS.

## Things you Wanted to Know – the Bottom Line

- What is IBS? IBS is a chronic disorder in which impaired function of the intestines causes chronic abdominal pain and irregular bowel movements.

- What is a chronic disease? A disease that persists for a long time and cannot be completely cured.
- Is IBS a chronic disease? IBS meets the criteria for a chronic disease.
- What’s the good news? IBS is not life threatening. IBS can be treated with the aim of:
  - o Enhancing coping skills.
  - o Reducing symptoms.
  - o Improving quality of life.

## More about the Book and the Author

The book’s chapters begin by describing the symptoms felt by IBS patients and explaining the structure and function of the digestive tract and how IBS is diagnosed. Later chapters present the causes of IBS, the central role played by the association between the gut and the brain in experiencing the symptoms of IBS and dealing with them, and “sister” functional disorders in other body systems that are very similar to IBS in their essence and their impact on patients. It then goes on to discuss treatment for IBS, from the aims of treatment and the importance of the therapeutic relationship between doctor and patient to different treatment options, including medication, psychological therapy, complementary and alternative medicine, nutrition, and combination therapy. It presents in detail things that patients can do to improve their relationship with their doctor and their chances for successful treatment and closes by discussing potential new developments in treatment for IBS.

Dr. Sperber was born and raised in New York City and immigrated to Israel at the age of 23. In 1981 he received his M.D. from the medical school of Ben-Gurion University, and completed a Master of Science in Public Health (M.S.P.H.) degree in 1992 from the Department of Health Behavior and Health Education in the School of Public Health of the University of North Carolina at Chapel Hill. In addition to patient care, Dr. Sperber has conducted extensive research on IBS as well as on co-existing conditions.





## Research News You Can Use

Here are summaries of some recent news about research and treatments for digestive health conditions.

### FDA Approves New Treatment for GERD

On March 27, 2012 Torax Medical announced that the U.S. Food and Drug Administration (FDA) approved the LINX Reflux Management System, a medical device for treating gastroesophageal reflux disease (GERD). The LINX System uses a small, implantable device to prevent the back-flow of stomach contents (reflux) in people with GERD who have not been helped by other treatments.

The LINX System is comprised of interlinked titanium beads with magnetic cores. The magnetic attraction between the beads augments the existing lower esophageal sphincter's (LES) barrier function to prevent reflux. The device is implanted with a standard minimally invasive laparoscopic procedure.

Torax conducted a feasibility study of 44 patients at four centers with a five-year follow-up plan. In addition, the company conducted a pivotal study of 100 patients at 14 centers with a five-year follow-up plan. Patients enrolled had GERD and chronic GERD symptoms, despite medical therapy. Results from both the feasibility and pivotal trials indicate that the benefits obtained with the LINX Reflux Management System outweigh its risks.

The most common side effects experienced with the LINX included difficulty swallowing, pain when swallowing food, chest pain, vomiting, and nausea.

Torax said that they will work with medical centers that have a specific expertise in the treatment of reflux disease to create "Centers of Excellence" for the LINX System. Patients will have access to the LINX procedure within the next 30 days.

### FDA Issues Safety Alert Regarding PPI Risk Factor

On February 8, 2012 the U.S. FDA issued a notice recommending that patients taking the stomach acid drugs known as proton pump inhibitors (PPIs) should immediately contact their healthcare professional and seek care if they develop diarrhea that does not improve. The FDA notice states that PPIs may be associated with an increased risk of *Clostridium difficile*-associated diarrhea. These PPIs include:

- AcipHex (rabeprazole sodium)
- Dexilant (dexlansoprazole)
- Nexium (esomeprazole magnesium)
- Omeprazole (omeprazole) Over-the-Counter (OTC)
- Prevacid (lansoprazole) and OTC Prevacid 24hr
- Prilosec (omeprazole) and OTC
- Protonix (pantoprazole sodium)
- Vimovo (esomeprazole magnesium and naproxen)
- Zegerid (omeprazole and Sodium bicarbonate) and OTC

Proton pump inhibitors are marketed under various brand and generic drug names as prescription and over-the-counter

(OTC) products. They work by reducing the amount of acid in the stomach. Prescription PPIs are used to treat conditions such as gastroesophageal reflux disease (GERD), stomach and small intestine ulcers, and inflammation of the esophagus. Over-the-counter PPIs are used to treat frequent heartburn. The FDA is also reviewing the risk in users of histamine H2 receptor blockers.

*Clostridium difficile* (*C. difficile*) is a bacterium that can cause diarrhea that does not improve. Symptoms include watery stool, abdominal pain, and fever, and individuals may go on to develop more serious intestinal conditions. The disease can also be spread in hospitals.

You should immediately contact and seek care from your healthcare professional if you...

- take PPIs and experience diarrhea that does not improve
- experience watery stool that does not go away, abdominal pain, and fever while taking PPIs

Your healthcare professional may order laboratory tests to check if you have *Clostridium difficile*-associated diarrhea.

### Additional Information for Patients and OTC Consumers:

- Do not stop taking your prescription PPI drug without talking to your healthcare professional.
- Discuss any questions or concerns about your PPI drug with your healthcare professional.
- If you take an OTC PPI drug, follow the directions on the package carefully.
- Report any side effects you experience to the FDA MedWatch program online at: [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm).

The FDA also recommends talking to your doctor about using the lowest dose and shortest duration of PPI therapy appropriate to the condition for which you are being treated.

### Understanding the Underlying Disease Process of Gastroparesis

#### Changes in Stomach Cells Associated with Two Forms of Gastroparesis

Researchers have found evidence of changes at the cellular level in the stomachs of individuals with gastroparesis, yielding new insights into this digestive disorder. Gastroparesis is a chronic condition characterized by impaired "motility" – the muscular contractions that move food along the gastrointestinal tract. This limited motility results in delayed food emptying from the stomach into the intestines, as well as many symptoms that compromise quality of life, including nausea, vomiting, bloating, weight loss, and abdominal pain. Gastroparesis is commonly associated with diabetes, which is thought to damage nerves connecting to the stomach that control muscular contractions.

However, often the cause of the disorder is unknown or “idiopathic.” Clinical studies on this disorder have been limited.

The finding... sheds light on the underlying disease processes at work in both forms of gastroparesis, and paves the way for future therapeutic development.

Scientists in the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Gastroparesis Clinical Research Consortium are now conducting research at sites across the nation to improve understanding of disease processes and develop effective treatments for this disorder. For this study, they collected stomach tissue samples from individuals with diabetic and idiopathic forms of gastroparesis, as well as control samples from patients undergoing gastric bypass surgery who did not have gastroparesis, in order to compare their cellular structures. Scientists identified the types of cells in each sample and noted any cell damage. Researchers noticed cellular abnormalities in the majority of samples from patients with either diabetic or idiopathic gastroparesis. The most frequent type of abnormality seen in stomach tissue from gastroparesis patients was a reduction in the number of interstitial cells of Cajal (ICCs), which play an important role as “pacemakers,” controlling muscular contractions in the stomach. Another common alteration was seen in the shape and increased number of immune cells present in the muscle layer. Some alterations in the gut nervous system were also observed.

In addition to seeing certain cellular changes the researchers observed lack of visible contact between ICCs and neighboring nerve or muscle cells. Some unique cellular features were also noted between diabetic and idiopathic gastroparesis.

This Consortium study represents the most comprehensive, clinical study of diabetic and idiopathic gastroparesis to date. The finding of cellular abnormalities in the stomachs of most individuals with this disorder – including changes in the structure and number of ICCs, nerve cells, and immune cells – sheds light on the underlying disease processes at work in both forms of gastroparesis, and paves the way for future therapeutic development. Future research by the Consortium members will continue to explore these abnormalities, such as how loss of contact among these cells might translate into the limited gastrointestinal motility seen in patients with gastroparesis.

Adapted from: *NIDDK Recent Advances & Emerging Opportunities*. February 2012. Source: Grover M, Farrugia G, Lurken MS, et al. Cellular changes in diabetic and idiopathic gastroparesis. *Gastroenterology*. 140:1575-1585, 2011.

## Bloating is an Important Symptom in Gastroparesis

Nausea and/or vomiting, early fullness or loss of appetite, and stomach pain are symptoms commonly related to gastroparesis. But other symptoms may also be prominent. A study reported by researchers on behalf of the NIDDK Gastroparesis Clinical Research Consortium investigated the prevalence of bloating in gastroparesis as well as its severity and impact on quality of life. They concluded that bloating

is prevalent and is severe in many patients with gastroparesis. The researchers gathered data from 335 gastroparesis patients. They found that bloating in gastroparesis is linked to the intensity of other symptoms, including nausea, fullness following a meal, abdominal pain, and altered bowel function. They also observed that as bloating worsens it increasingly impairs quality of life independent of gastric emptying rates.

In gastroparesis, the symptom of bloating is often underappreciated. A better understanding of this symptom will lead to improved treatment and management in individuals with the condition.

Source: Hasler WL, et al. Bloating in gastroparesis: severity, impact and associated factors. *Am J Gastroenterol*. 2011 Aug; 106(8):1492-502.

## New Discoveries in Children with IBS about Bacteria in the Gut

Researchers have found that certain mixes of intestinal bacteria are associated with pediatric irritable bowel syndrome (IBS). IBS symptoms, which include abdominal pain, constipation and/or diarrhea, gas, and bloating, can make this a difficult and debilitating syndrome for children. At this time, the cause of IBS is unknown. IBS is less defined in children than adults, and there are limited treatments for either adults or children. Researchers have now looked to children's intestinal bacteria for clues to a cause and possible treatment of this syndrome.

For this study, the researchers compared the intestinal bacteria populations of 22 children with IBS to those of 22 children without IBS. All of the children were between the ages of 7 and 12 years. Over a 2-week period, the children collected stool samples for the study and entered a description of any pain associated with the stool in diaries. From the stool samples, the researchers isolated and sequenced the DNA (genetic components) of all the bacteria present, which is known as the “microbiome.” Researchers were then able to analyze the volume, species, and size of each type of bacteria population.

Comparisons of the microbiomes showed that the children with and without IBS had similar total numbers of intestinal bacteria. However, in the children with IBS, certain types of bacteria made up a greater percentage of the total. In addition, the researchers were able to distinguish between two pediatric IBS subtypes – IBS with constipation and IBS unsubtyped – by analyzing the composition of the bacteria in samples from children with IBS and the pain that they described in their diaries. Based on differences in bacteria and recurrent abdominal pain associated with pediatric IBS, the researchers developed “microbial signatures” associated with IBS in children and its unique subtypes.

This pioneering study presents important insights into the relationship of pediatric IBS and intestinal bacteria. Further research may lead to improvements in diagnosing and treating the condition.

Adapted from: *NIDDK Recent Advances & Emerging Opportunities*. February 2012. Source: Saulnier DM, Riehle K, Mistretta TLA, et al. Gastrointestinal microbiome signatures of pediatric patients with irritable bowel syndrome. *Gastroenterology* 141: 1782-1791, 2011.



# Be an Active Member of Your Health Care Team

When it comes to using medicine, it is important to know that no medicine is completely safe. The U.S. Food and Drug Administration (FDA) judges a drug to be safe enough to approve when the benefits of the medicine outweigh the known risks for the labeled use.

Doctors, physician assistants, nurses, pharmacists, and you make up your health care team. To reduce the risks from using medicines and to get the most benefit, you need to be an active member of the team.

## To make use of medicine SAFER:

- Speak up
- Ask questions
- Find the facts
- Evaluate your choices
- Read the label and follow directions

## Speak up

The more information your health care team knows about you, the better the team can plan the care that's right for you.

The members of your team need to know **your medical history**, such as illnesses, medical conditions (like high blood pressure or diabetes), and operations you have had.

They also need to know **all the medicines and treatments you use**, whether all the time or only some of the time. Before you add something new, talk it over with your team. Your team can help you with what mixes well, and what doesn't.

It helps to give a **written list** of all your medicines and treatments to all your doctors, pharmacists and other team members. Keep a copy of the list for yourself and give a copy to a loved one.

## Be sure to include:

- prescription medicines, including any samples your doctor may have given you
- over-the-counter (OTC) medicines, or medicines you can buy without a prescription (such as antacids, laxatives, or pain, fever, and cough/cold medicines)
- dietary supplements, including vitamins and herbs
- any other treatments
- any allergies, and any problems you may have had with a medicine

- anything that could have an effect on your use of medicine, such as pregnancy, breast feeding, trouble swallowing, trouble remembering, or cost

## Ask Questions

Your health care team can help you make the best choices, but you have to ask the right questions. When you meet with a team member, have your questions written down and take notes on the answers. You also may want to bring along a friend or relative to help you understand and remember.

Use the Question Guide at the end of this article to help you get the answers you need from your health care team. If you don't understand an answer, ask again.

## Find the Facts

Before you and your team decide on a prescription or OTC medicine, learn and understand as much about it as you can, including:

- brand and generic (chemical) names
- active ingredients – to make sure that you aren't using more than one medicine with the same active ingredient
- inactive ingredients – if you have any problems with ingredients in medicines, such as colors, flavors, starches, sugars
- uses (“indications” and “contraindications”) – why you will be using it, and when the medicine should/should not be used
- warnings (“precautions”) – safety measures to make sure the medicine is used the right way, and to avoid harm
- possible interactions – substances that should not be used while using the medicine. Find out if other prescription and OTC medicines, food, dietary supplements, or other things (like

alcohol and tobacco) could cause problems with the medicine

- side effects (“adverse reactions”) – unwanted effects that the medicine can cause, and what to do if you get them
- possible tolerance, dependence, or addiction – problems that some medicines can cause, and what you can do to avoid them
- overdose – what to do if you use too much
- directions – usual dose; what to do if you miss a dose; special directions on how to use the medicine, such as whether to take it with or without food
- storage instructions – how and where to keep the medicine
- expiration – date after which the medicine may not work, or may be harmful to use

Your pharmacy, the library, the bookstore, the medicine maker, and the Internet have medicine information made for consumers. If you have questions, ask your health care team.

## Evaluate your Choices – Weigh the Benefits and Risks

After you have all the information, think carefully about your choices. Think about the helpful effects as well as the possible unwanted effects. Decide which are most important to you. This is how you weigh the benefits and risks. The expert advice from your health care team and the information you give the team can help guide you and your team in making the decision that is right for you.

## Read the Label and Follow Directions

Read the label to know what active ingredient(s) is (are) in the medicine.





The active ingredient in a prescription or OTC medicine might be in other medicines you use. Using too much of any active ingredient may increase your chance of unwanted side effects.

Read the label each time you buy an OTC medicine or fill your prescription. When buying an OTC, read the “Drug Facts” label carefully to make sure it is the right medicine for you. Prescription and OTC medicines don’t always mix well with each other. Dietary supplements (like vitamins and herbals) and some foods and drinks can cause problems with your medicines too. Ask the pharmacist if you have questions.

Before you leave the pharmacy with your prescription, be sure you have the right medicine, know the right dose to use, and know how to use it. If you’ve bought the medicine before, make sure that this medicine has the same shape, color, size, and packaging. Anything different? Ask your pharmacist. If your medicine tastes different when you use it, tell your health care team.

## **Read and Save all the Information you get with your Medicine.**

**Read the label each time before you use the medicine. Be sure it’s right in 5 ways:**

1. the right medicine
2. for the right patient
3. in the right amount
4. at the right time
5. in the right way (for example, swallow instead of chew a pill)

Follow directions on the label and from your health care team. When you are ready to use the medicine, make the most of the benefits and lower the risks by following the directions.

If you want to stop a medicine your doctor told you to use or to use it in a different way than directed, talk to a team member. Some medicines take longer to show that they are working. With some medicines, such as antibiotics, it is important to finish the whole prescription, even if you feel better sooner. When you stop using some medicines, you must reduce the dose little by little to prevent unwanted side effects.

## **Report Back to the Team**

Pay attention to how you feel. If you have an unwanted effect, tell your health care team right away. A change in the dose or a change in medicine may be needed.

## **Question Guide**

Use this guide with your health care team to find out what you need to know about the medicines you use, and about the medicines you are thinking about using. Be sure to find the answers to these questions for any sample medicine your doctor gives you.

- What are the brand and generic (non-brand) names of the medicine?
- What is the active ingredient?
- Could I use a generic form?
- What is the medicine for, and what will it do for me?
- When should I start to feel better?
- When should I report back to the team?
- Will this medicine take the place of any other medicine I have been using?
- Should I avoid any drinks, foods, other substances, or activities while using this medicine?
- Can this medicine be used safely with the other medicines and treatments I already use? Does this include prescription and OTC medicines, vitamins, herbals, or other supplements, and other treatments?
- Should I avoid starting other medicines (prescription or OTC), dietary supplements (like herbals and vitamins) or other treatments while I am using this medicine?
- What are the possible side effects from this medicine? What do I do if I get a side effect?
- Is there any chance that I could become tolerant, dependent or addicted to this medicine? What can I do to avoid this?
- How and when should I use the medicine, in what amount, and for how long? Are there any special directions for using this medicine?
- Will I need any tests (blood tests, x-rays, other tests) to make sure the medicine is working as it should? How will I get the results?

- What should I do if I miss a dose? What should I do if I use too much by mistake?
- How and where should I keep this medicine? (Remember: Always put medicines out of the sight and reach of children and pets.)
- Where and how can I get more information about this medicine?

**Remember:** To reduce the risks of using medicines and to get the most benefit, you need to be an active member of your health care team.

U.S. Department of Health and Human Services  
Food and Drug Administration  
[www.fda.gov/drugs](http://www.fda.gov/drugs)  
1-888-INFO-FDA

Council on Family Health  
[www.cfbinfo.org](http://www.cfbinfo.org)  
(FDA) 04-1503A  
4/2004

This article is not copyrighted. Source: FDA website. <http://www.fda.gov/Drugs/ResourcesForYou/ucm079453.htm> (accessed 03.19.12)



## 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.

**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 Saltrelli, 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:** IBS – Free at Last

**Author:** Patsy Catsos, M.S., R.D.

**Publisher:** Pond Cove Press (2009)

**Pages:** 126 (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. This approach is based on research, which has produced strong evidence that a group of short-chain carbohydrates, named 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 dietary sugars, starches, and fibers and IBS symptoms. It includes menus, tips on shopping and reading labels, and strategies for including your favorite foods in your diet. 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.





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 are pleased to welcome the newest members of the IFFGD Industry Council: Furiex Pharmaceuticals, and NPS Pharmaceuticals.

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

### Ironwood and Forest Report the U.S. FDA has Accepted for Review the New Drug Application for Linaclotide for the Treatment of Irritable Bowel Syndrome with Constipation and Chronic Constipation

Linaclotide is a drug being studied to relieve symptoms of abdominal pain, discomfort, bloating, and bowel symptoms in people who have irritable bowel syndrome with constipation (IBS-C), or chronic constipation. It has proved safe and effective in trials, and has recently been submitted to the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for approval in the United States and in Europe. Linaclotide works by increasing the amount of fluid that flows into the bowel, allowing stool to pass more easily, and reducing visceral pain.

On October 24, 2011 Ironwood Pharmaceuticals, Inc. and Forest Laboratories, Inc. announced that the FDA accepted for review the New Drug Application (NDA) for linaclotide, a guanylate cyclase type-C (GC-C) agonist, to treat irritable bowel syndrome with constipation (IBS-C) and chronic constipation (CC). The review, which will determine whether or not the FDA approves the drug, has a target date of September 2012.

The NDA includes efficacy and safety data from a Phase 3 program comprising four double-blind placebo-controlled trials and two open-label long term safety studies. A total of more than 2,800 patients received a once-daily dose of either linaclotide or placebo across the four placebo-controlled clinical trials: two trials in patients with IBS-C and two trials in patients with chronic constipation. In these trials, statistically significant improvements in abdominal and bowel symptoms were achieved for linaclotide-treated patients versus placebo-treated patients for all primary and secondary endpoints.

Safety data collected across the four placebo-controlled Phase 3 clinical trials demonstrated that diarrhea was the most commonly reported adverse event and led to study discontinuation in 4% to 5% of linaclotide-treated patients compared to fewer than 1% of patients receiving placebo. Additionally, over 3,200 patients have enrolled in ongoing open-label safety studies and more than 1,100 of those patients have received linaclotide for at least 12 months.

In September 2011, Ironwood announced that its European partner Almirall, S.A. submitted a Marketing Authorization Application (MAA) to the European Medicines Agency for linaclotide for the treatment of irritable bowel syndrome with constipation. Once approved, linaclotide will be marketed in Europe under the trademark Constella®.

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



## 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 (Non-C IBS) 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 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 U.S. Food and Drug Administration (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. The FDA has set a target date of March 7, 2011 to complete the Priority Review for expanding the uses of Xifaxan (rifaximin) to include treatment of non-constipation irritable bowel syndrome (Non-C IBS) and IBS-related bloating.



## Lubiprostone Results Positive in Treating Opioid-Induced Bowel Dysfunction

On February 2, 2012 Sucampo Pharmaceuticals, Inc. and Takeda Pharmaceuticals USA, Inc. announced that 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. Others symptoms may include decreased gastric emptying, abdominal cramping, spasm, bloating, and delayed GI transit.

This 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. Submission of a supplemental New Drug Application to the U.S. Food and Drug Administration (FDA) for lubiprostone to treat opioid-induced bowel dysfunction is anticipated in the first half of 2012.

## 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

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

Gattex (teduglutide) is a drug currently under investigation 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 January 31, 2012 NPS Pharmaceuticals, Inc. announced that the FDA has accepted and filed for review the company's New Drug Application (NDA) for Gattex for the treatment of adults with short bowel syndrome.

The acceptance of the Gattex NDA is the FDA's determination that the application is sufficiently complete to permit a substantive review.

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. The initial NDA included data from 75 SBS subjects who had at least 12 months of exposure to Gattex. Side effects include abdominal pain, nausea, gastrointestinal stoma complications, and abdominal distension.

People with SBS are highly prone to malnutrition, diarrhea, dehydration, and an inability to maintain weight due to the reduced intestinal capacity to absorb macronutrients, water, and electrolytes. As a result, many patients require the long-term use of parenteral nutrition (PN) and intravenous (IV) fluids to supplement their nutritional needs and stabilize their hydration. Although PN/IV can meet basic nutrition and fluid requirements, it does not improve the body's ability to absorb nutrients.

The long-term use of PN/IV fluids is associated with serious and life-threatening complications. Patients on parenteral support often experience a poor quality of life with difficulty sleeping, frequent urination, and loss of independence.

### **Furiex Reports Positive Phase 2 Results for MuDelta in Treatment of Diarrhea-Predominant Irritable Bowel Syndrome**

MuDelta is a novel drug under development for the treatment of irritable bowel syndrome with diarrhea as the predominant bowel symptom (IBS-D). The drug was designed with the purpose of treating both the diarrheal and pain symptoms of IBS-D.

A completed Phase 2 proof-of-concept clinical trial evaluated the safety and efficacy of MuDelta. In the study, MuDelta was well-tolerated and had a favorable safety profile.

The drug met its primary objectives of establishing tolerability, safety, and efficacy in a 12-week randomized, double-blind, placebo-controlled study. The study achieved statistically and clinically significant results for its primary as well as a number of key secondary endpoints. MuDelta also demonstrated durable efficacy through the 12-week treatment period.

A total of 807 patients with IBS-D were enrolled in the phase 2 trial. The primary endpoint was a composite analysis of stool consistency and abdominal pain at week four compared with baseline symptoms. The study demonstrated that treatment with MuDelta was statistically superior to placebo for this primary endpoint.

The compound now has an agreed-upon, clear regulatory path forward with the U.S. Food and Drug Administration (FDA). The drug has been granted fast-track status by the FDA in acknowledgement of the potential to address a significant unmet medical need for patients with IBS-D.

Phase 3 trials will begin next to accumulate data that further evaluates the drug's safety and effectiveness.

Furiex Pharmaceuticals, Inc. is developing MuDelta under a November 2009 development and license agreement with Janssen Pharmaceutica N.V.

### **What are Phases?**

**Treatment trials or studies are in four phases:**

- Phase 1 tests a new drug or treatment in a small group to evaluate its safety, determine a safe dosage range, and identify side effects;
- Phase 2 expands the study to a larger group of people to see if it is effective and to further evaluate its safety;
- Phase 3 expands the study to an even larger group of people to confirm its effectiveness, monitor side effects, and collect information that will allow the drug or treatment to be used safely; and
- Phase 4 takes place after the drug or treatment has been licensed and marketed to further evaluate it in the general population.

## Professional Announcements

### Qualified Investigators Sought for Phase 3 Clinical Trial Participation

**Official Title:** Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Efficacy, Safety, and Tolerability of JNJ-27018966 in the Treatment of Patients with Diarrhea-Predominant Irritable Bowel Syndrome (IBS-d); Protocol Numbers 27018966IBS3001/3002

**Purpose of Trial:** To evaluate the efficacy, safety, and tolerability of JNJ-27018966 compared with placebo in the treatment of patients with diarrhea-predominant irritable bowel syndrome.

**Sponsored by:** Furiex Pharmaceuticals, Morrisville, North Carolina

**Contact:** 1-877-345-2145

More trial details may be found at <http://clinicaltrials.gov/ct2/results?term=JNJ-27018966>

### 7th Postgraduate Course on Gastrointestinal Motility and Neurogastroenterology in Clinical Practice

The American Neurogastroenterology and Motility Society will hold this meeting on **July 27–29, 2012 in Chicago, IL.**

Meeting highlights include:

- Live demonstrations of esophageal and anorectal manometry, breath tests, and wireless motility capsule
- Pediatric motility
- Workshops by renowned faculty
- Dedicated workshops for nurses, trainees, & beginners
- Young investigator forum

Details and Registration Information:  
[www.motilitysociety.org](http://www.motilitysociety.org)

### Joint International Neurogastroenterology and Motility Meeting

The European Society of Neurogastroenterology and Motility (ESNM) and the American Neurogastroenterology and Motility Society (ANMS) will be holding this meeting on **September 6–8, 2012 in Bologna, Italy. (NGM2012).**

The purpose of this meeting is to bring together leading experts and emerging young investigators actively involved in neurogastroenterology, digestive motility, and functional gastrointestinal diseases from all around the world to discuss cutting-edge research.

Details and Registration Information:  
[www.ngm2012.org](http://www.ngm2012.org).

### IFFGD Seeking Applications for 2013 Research Awards

#### Guidelines

The International Foundation for Functional Gastrointestinal Disorders (IFFGD) is pleased to announce that we are seeking applications/nominations for research awards.

#### Basis

IFFGD will give awards to active investigators who have a record of research interest in basic mechanisms or clinical aspects of functional gastrointestinal and motility disorders, and neurogastroenterology. These awards are intended to encourage the participation of clinicians and scientists in multidisciplinary efforts aimed at advancing the understanding of these basic mechanisms or clinical aspects in adults and in children.

#### Eligibility and Award Amount

To be eligible, investigators must have completed an M.D. or Ph.D., have demonstrated research activities, and be currently active in investigating basic or

clinical aspects of functional GI or motility disorders, or neurogastroenterology. One award will be given in each of the following six categories, in the amount of \$7,500 respectively.

#### Research Categories

- **Senior Investigator** (10 years or more after receipt of highest degree)  
– Clinical Science
- **Senior Investigator** (10 years or more after receipt of highest degree)  
– Basic Science
- **Junior Investigator** (Less than 10 years after receipt of highest degree)  
– Clinical Science
- **Junior Investigator** (Less than 10 years after receipt of highest degree)  
– Basic Science
- **Pediatric Senior Investigator** (10 years or more after receipt of highest degree) – Clinical/Basic Science
- **Pediatric Junior Investigator** (Less than 10 years after receipt of highest degree) – Clinical/Basic Science

#### Application and Nomination

Applications are to be submitted on behalf of the candidate along with letters of sponsorship and support from clinicians or scientists who are familiar with the candidate's research activities. A letter of sponsorship from the nominating person, a second letter of support, and the CV of the nominee should accompany the application. The IFFGD Selection Committee will review applications and designate the awards.

#### Reporting

Each award recipient will be required to provide a brief article, to be published by IFFGD, which summarizes his or her current research objectives and progress.

#### Award Ceremony

The individuals selected for awards will be recognized at IFFGD's 10th International

## Seeking Applications Cont.

Symposium for Functional GI Disorders to be held in Milwaukee, WI on April 12–14, 2013. Awards are in pre-tax U.S. dollars.

### Deadline

The deadline for receipt of applications is October 1, 2012.

### Completed applications should be submitted to:

Selection Committee  
IFFGD  
700 W. Virginia St., Suite 201  
Milwaukee, WI 53204

### Application forms and details can be obtained from:

IFFGD  
700 W. Virginia St., Suite 201  
Milwaukee, WI 53204  
Phone: 414-964-1799  
Fax: 414-964-7176  
Email: [iffgd@iffgd.org](mailto:iffgd@iffgd.org)  
Web: [www.giresearch.org/awards](http://www.giresearch.org/awards)



*Scan this code with  
your smart phone for  
more informaton.*

## 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](http://www.iffgd.org/site/news-events/events/professional-symposia).

### For further information, contact:

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

**Or go to the IFFGD web page at**  
[www.iffgd.org/symposium](http://www.iffgd.org/symposium).



*Scan this code with  
your smart phone for  
more informaton.*



## Community News

### Courageous Stories

**It takes skill, strength, and courage for persons to meet the long-term challenges of chronic digestive disorders. Sharing experiences can be therapeutic for the writer as well as others who suffer. Whether you or a friend or family member has a disorder, we invite you to share your story. Write to us, or log on to our web sites.**

*Maddie's Courageous Story* – My first father's day was certainly not as I had imagined. We were in a strange city, in a huge hospital and within the upcoming days my wife, Tammy and I, would be making the most difficult decision so far in our lives. Our only child, Madelyn Kate made her entrance into our world ten months earlier on her due date August 22, 2007. I felt so ecstatic holding her that I found it difficult to breathe.

We realized that something was seriously wrong when Maddie began vomiting bile her second day of life and was unable to tolerate any feeding. Our roller coaster ride had begun. We were told that she "must have some sort of intestinal obstruction" and that surgery would likely be required. She was immediately transferred from the hospital to another medical center.

To everyone's surprise no true obstruction was found on Maddie's tests, but the transit time through her intestines was markedly delayed. We were told that it should simply be a matter of weeks for her intestines to mature before we could take her home.

Within days her tummy became so distended it looked like she had a water melon in it and she screamed in pain. A tube was inserted down thru her nose and taped to her face to drain the stomach contents so that she wouldn't have to vomit them. When the vomiting would quell for an hour or more they attempted feeding through this same tube, a few drops at a time to no avail. We could no sooner get her clean and dry that she would vomit again. We felt helpless, desperate, and frustrated!

After 3 weeks with no improvement, Maddie was flown to one of the top 5 children's hospitals in the country. We spent another few weeks trying to increase feeds by mouth and feeding tube. Maddie was tested for every disease and disorder they could think of. They tried numerous medications but nothing helped. One positive word or sign or test result would give us the strength to pull ourselves out of the next ditch we were thrown into with bit of bad news. We overheard one doc tell another, "we've given up feeding her" and we were heartbroken.

In the absence of a cause for Madelyn's intestinal failure, a tentative diagnosis of chronic intestinal pseudo obstruction was made. Chronic intestinal pseudo-obstruction (CIP) is a rare disorder of gastrointestinal motility where coordinated contractions (peristalsis) in the intestinal tract become altered and inefficient. When this happens, nutritional requirements cannot be adequately met.

At 6 weeks old she had 4 full thickness small intestine biopsies and her first central line placed. A central line is a tiny catheter that is place in a vein just under the skin in the chest and then threaded through the blood vessel all the way to the tip of the heart. All of her nutrition would now go through this IV line. It was around this time that my wife asked one of the doctors "is pseudo-obstruction something that could kill her?" The reply was, "I don't think we can answer that just yet."



Madelyn had been on TPN (total parental nutrition or IV nutrition) 24 hours a day since shortly after birth. This was causing liver damage and she was shockingly jaundiced. The catch 22 with TPN and a central line is that although it gives the nutrition needed to survive, it can cause the liver to fail and/or life threatening blood infections, metabolic bone disease, and anemia. Incredibly, we found a pediatric GI motility expert (one of a handful in the country) about 2 hours away, who we were able to speak to at length on the phone. When Maddie was 10 weeks old this doctor was able to perform a test that would give us a definitive diagnosis of intestinal pseudo-obstruction. We felt relief that we knew what to call it, but devastated that there is no cure and that she would be "chronically ill" for life.

She was in surgery the next day to have a permanent feeding tube put in her stomach, an ileostomy placed and more intestinal biopsies. The "feeding" tube allows us to drain the bile and formula (or food) that has backed up into her stomach as needed to hopefully prevent vomiting. She had a very difficult time recovering from surgery. Two days before Thanksgiving we were able to take her home for the first time. She was on 20 hours of TPN per day and pre digested formula mixed ½ strength continuously running through her feeding tube.

Learning to handle her IV nutrition, tube feeds, and ostomy care was terrifying, even with the help of grandparents, other family, and many friends. We rarely slept more than 2 hours at a time and it was very hard to think straight. The first year she threw up about 30 times a day, around the clock. We were told that if Maddie made it through the first year of life that she would probably do well. The statistics are that 1/3 of infants with pseudo-obstruction on TPN die within the first year due to liver failure or blood infection.

Maddie's liver disease was significant enough that we were referred for a small bowel/pancreas/liver transplant evaluation when she was 10 months old. They were very concerned that her liver was near failure. It was during this transplant evaluation that we "celebrated" my 1st Fathers Day. The transplant surgeon said point blank, "your daughter has a fatal disease, not unlike cancer, and a transplant is her best chance at long term survival."

We were completely shocked. The one year survival rate for this transplant was 90% and five year survival rate 60%. We were in the process of getting FDA approval for two investigational drugs used only for emergency or life saving purposes. After much careful consideration, prayer, and counsel from our two GI doctors we chose not to list her for multi-organ transplant at the time. We chose to continue to "limp along" as we had been. Over the next three months Maddie's bilirubin and liver function tests miraculously started to normalize. Although we had finally received FDA approval for both emergency drugs we only needed one of them.

The first year of her life wasn't marked by weeks or months of age, but by which hospital we were at. Ultimately, we spent the first year of her life in 8 different hospitals in 5 different states. It was the most difficult year of our lives. We pray to never suffer the pain that we experienced during that first year, ever. We have been fortunate that an intestinal failure team has been set up at a nearby hospital and they work closely with our GI motility specialist as needed.

Maddie is three and one-half years old now and is on 18 hours per day of TPN. She is allowed to eat small amounts of certain foods by mouth for pleasure. It is important that she not develop any food or eating aversion. We have never been successful with tube feeding even a teaspoon per hour. She is treated for her anemia with weekly IV Iron Infusions and is on constant rotating antibiotics for small bowel bacterial overgrowth. She has emergency approval for the drug Zelnorm, which she gets 2 times per day.

Some people can tolerate TPN for many, many years. Some children have a difficult time growing while on it. So far Maddie has not. We take it one day at a time and sometimes five minutes at a time. We try not to live in constant fear but sometimes it is very difficult. Each fever takes our minds on an odyssey to its darkest corners where no parent should have to travel. A place that most parents don't ever have to experience and those that do usually don't speak of. Is this the fever that points to a line infection that leads to a sepsis "the number one killer of children on TPN" that kills MY child?

The what if's take over, more so when we are tired and feeling desperate. She sleeps in the bed next to ours and we love having her so close to us. We do not ever want to regret not spending even five minutes with her. Our life is about her and we thank God daily for giving us the opportunity to take care of her and for all the joy she brings to our family and friends. She has changed many lives. We

pray for better transplant outcomes, a stem-cell breakthrough, or cure, and better drugs to treat motility disorders.

This next father's day certainly won't be as I had imagined. We have just returned from a strange city, after staying near a magical place called Disney World. We are so thankful to Make a Wish Foundation and Give Kids the World for making Maddie's wish to meet princesses, like herself, in person.

Will pseudo-obstruction kill her? We don't know the answer to that yet. What we do know is that miracles do occur, dreams do come true and wishes are granted. And we are so thankful for our family and friends who have helped us immensely along the way.

—[DHA.org/stories](http://DHA.org/stories)





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

## DHA Advocacy Day 2012

Advocates are people who speak out about something they believe in on behalf of themselves and/or others.

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

In addition to sharing personal stories, advocates will urge Members of Congress to take action in important initiatives, like funding federal Functional GI and Motility Disorders research activities. *This includes 4 specific and critical issues:*

- House Member co-sponsorship of the **Functional Gastrointestinal and Motility Disorders Research Enhancement Act of 2011 (H.R. 2239)**.
- Senate support of **increased funding for the National Institutes of Health (NIH)** to a level of at least \$32 billion in Fiscal Year 2013. (See more on this issue below.)
- **Support veterans** in the FY13 Defense Appropriations bill by House and Senate funding support of the Department of Defense Peer-Reviewed Gulf War Illness Research Program, which provides a source of funding for functional GI disorders research.
- House and Senate support to ensure passage of the **Pediatric Research Consortia Establishment Act (H.R. 1080)**.

Our 2012 Advocacy Day will take place on June 19–20, 2012 in Washington, DC. If you plan to attend, you will need to register with IFFGD/DHA by **Monday, May 28th**.

### Register online at:

[www.dha.org/advocacy-day](http://www.dha.org/advocacy-day)

There is no fee to participate in Advocacy Day; however participants are responsible for their own transportation and lodging expenses. Dinner on Tuesday night and breakfast on Wednesday morning will be provided.

### Hotel Information

We have a block of rooms reserved at The Phoenix Park Hotel on Capitol Hill for the special daily rate of \$330.00. **Make your reservations directly** by calling the hotel at 800-824-5419 or 202-638-6900. Be sure to mention that you are attending the “**DHA Advocacy Day 2012**” and mention “**Group Code 16535**.”

### Phoenix Park Hotel

520 North Capitol Street, N.W.  
Washington, DC 20001  
202-638-6900

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

## National Institutes of Health (NIH) Facing Budget Cuts in Fiscal Year 2013 that would Limit Biomedical Research

On August 1, 2011 the Budget Control Act of 2011 was signed into law. Over the next 10 years, the debt limiting law will reduce the federal budget deficit by an annual average of about 1 percent of gross domestic product – about 2.1 trillion dollars.

Under the law, the National Institutes of Health (NIH), the nation’s biomedical research agency, faces an automatic 7.8% or \$2.5 billion cut in their fiscal 2013 budget unless an alternative plan becomes law later this year to meet deficit reduction targets.

According to NIH Director Francis S. Collins, MD, PhD, the cut would mean NIH would be able to fund 2,300 fewer grants in fiscal 2013. Over the past nine years, with nearly flat budgets, NIH has lost purchasing power for medical research due to inflation. Only 1 out of 7 grant requests now get supported, the lowest ratio in NIH history.

### Impact on the Digestive Health Community

The NIH is the largest source of funding for medical research in the world. NIH support goes to scientists in universities and research institutions in every state and around the globe. Research findings are the basis for medical treatments and the search for cures. Continued research is critical to our community affected by digestive health conditions.

### Congressional Hearing

On Tuesday, March 20th, Dr. Collins, and the Acting Director of the recently established National Center for Advancing Translational Science (NCATS), Thomas R. Insel, MD, testified before the House Labor-Health and Human Services-Education (LHHS) Appropriations Subcommittee in regards to the President’s Fiscal Year (FY) 2013 budget request to Congress, which would continue NIH funding at the current 2012 level.

Dr. Collins’ testimony featured recent research advancements at NIH and touched on how research is a critical engine for economic development. In addition, both Dr. Collins and Dr. Insel spoke at length about the emerging opportunities NIH will be pursuing following the establishment of NCATS. This Center represents a realignment of existing NIH programs to improve the process of translating scientific findings into useful treatments, including working with industry.



Subcommittee member, Rep. Nita Lowey (D-NY), stressed that in FY 2013 NIH must be provided with at least \$32 billion, which is the increased funding level that the public health community, including IFFGD and DHA, is now advocating for. The current FY 2012 NIH budget is \$30.7 billion.

### What You can Do

Contact your Congressional representatives in the U.S. House and Senate. Ask them to support increased NIH funding at a level of \$32 billion for Fiscal Year 2013.

- Go online to our Legislative Action Center at [www.iffgd.org/action](http://www.iffgd.org/action).
- Click on NIH 2013 Budget Action to send an email on this issue to your representatives.

Be an advocate for digestive health. Thank you.

### Make the Functional GI & Motility Disorders Research Enhancement Act Law

On June 16, 2011 in the 1st session of the 112th Congress, H.R. 2239 – the Functional GI & Motility Disorders Research Enhancement Act – was introduced in the U.S. House of Representatives. To become law, it needs to pass with a majority in the House, and also be introduced and passed by a majority in the Senate.

### We've Made Taking Action Easy for You

You can now send an impactful email to your House Member urging support of H.R. 2239 online at [www.iffgd.org/2239action](http://www.iffgd.org/2239action). Just go to the page, enter your Zip code, complete your email, and send. In a matter of seconds, you can help change the world for sufferers of functional GI and motility disorders. Act now.

To make this happen, **it is essential that you contact your representative** in the House (and later in the Senate.) Here is why.

Members of Congress introduce thousands of bills each year. Only a few get the attention we see in the news, for example, as Members negotiate and then vote on tax bills or budget bills that attract national attention. H.R. 2239 is not that kind of bill; most people have no idea what a functional GI or motility disorder is. This bill will not be discussed by politicians on Sunday morning talk shows; it likely will not be brought to the floor of the House in a vote to be reported on the nightly news. Instead, Members will cosponsor the bill and when a majority is reached it will have passed. The beauty of this process is that the people that care about this issue – you – have the power to make it happen. But you must contact your House Member (and later Senators) to make it happen.

*This bill is revenue neutral* – it does *not* add to the national debt. It is receiving bi-partisan support. If your Member of Congress has not cosponsored it yet, it is probably because he or she has not been asked to do so by constituents.

Take action. Make your Representative aware of the importance of this bill and ask them to become a cosponsor. By speaking out, you 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 every day.

When you reach out as a constituent, you put a face on those affected by functional GI and motility disorders; you add meaning to what

could be just another piece of legislation coming across a desk. Your action, along with your fellow advocates, will see that this bill is passed!

Sometimes, all it takes is a few people reaching out to a representative to persuade that Member of Congress to act. Your one voice matters!

### Why This Bill is Important to You

In addition to raising critical awareness of functional GI and motility disorders and the needs of patients, passage of this landmark legislation will...

- Grant the National Institutes of Health (NIH) new authority to initiate innovative research projects
- Establish a Centers of Excellence Program in this area
- Coordinate research activities with the Department of Defense and the Veterans Administration when appropriate
- Call on the Food and Drug Administration (FDA) to improve review, approval, and oversight of treatments for FGIMDs

### Summary of H.R. 2239:

Amends the Public Health Service Act to require the Director of the National Institutes of Health (NIH) to expand, intensify, and coordinate NIH activities with respect to functional gastrointestinal and motility disorders (FGIMDs), including by:

1. Expanding basic and clinical research into FGIMDs by implementing the research recommendations of the National Commission on Digestive Diseases,
2. Providing support for the establishment of centers of excellence on FGIMDs
3. Exploring collaborative research opportunities among the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), Office of Research on Women's Health, Office of Rare Disease Research, and other NIH Institutes and Centers
4. Directing the NIDDK to provide the necessary funding for the continued expansion and advancement of the FGIMDs research portfolio through intramural and extramural research,
5. Directing such Institute and the Eunice Kennedy Shriver National Institute of Child Health and Human Development to expand research into FGIMDs that impact children, and
6. Exploring opportunities to partner with the Dept of Defense and Dept of Veterans Affairs to increase research and improve patient care regarding FGIMDs that commonly impact veterans and active duty military personnel.
7. Authorizes the Secretary of Health and Human Services (HHS) to engage in public awareness and education activities to increase understanding and recognition of FGIMDs.
8. Expresses the sense of Congress that the FDA continue and accelerate important efforts to improve the development and oversight of treatment options for FGIMDs.



21

### These House Members have cosponsored the bill:

Rep. F. James Sensenbrenner, Jr. (R-WI-5)	Rep. Tammy Baldwin (D-WI-2)
Rep. James Moran (D-VA-8)	Rep. Maurice Hinchey (D-NY-22)
Rep. Peter Welch (D-VT)	Rep. Gwen Moore (D-WI-4)
Rep. Elton Gallegly (R-CA-24)	Rep. Nan Hayworth, M.D. (R-NY-19)
Rep. Jesse Jackson, Jr. (D-IL-2)	Rep. David E. Price (D-NC-4)
	Rep. Ed Perlmutter (D-CO-7)

## Community News Cont.



### Raising Awareness

During IBS Awareness Month in April, and in following months, look for public service announcements (PSAs) to air on radio and TV. The PSAs will raise awareness about IBS. They also encourage people with symptoms to talk to their health care providers and take an active approach to managing their condition.

The PSAs feature the personal experience of an IBS patient and comments from a physician. IFFGD was able to produce the PSAs in partnership with Takeda Pharmaceuticals and Sucampo Pharmaceuticals.

## DHA Children's GI Research Network

### You can Help Find Cures for Children

Many children suffer with painful, disabling, and in some cases life-threatening functional GI and motility disorders (FGIMDs). Most of these conditions progress into adulthood, becoming more costly and difficult to manage.

The DHA Children's GI Research Network carries out research projects and advances science in order to improve diagnosis and treatment of childhood FGIMDs.

You can make a difference by supporting the Network with your donation. Go to our web page at [www.dha.org/content/kids-gi](http://www.dha.org/content/kids-gi) to find out more and how you can help. You can donate online or by contacting IFFGD. Thank you.

## Personal Advocacy

Through the DHA, the grassroots arm of IFFGD, you can organize your own advocacy campaigns. Here is one example.

### Grant's Story

Grant is a delightful 5-year-old with GI issues. From birth he suffered with pain and distension. Treatments were ineffective.

Grant was sick and his parents were exhausted when, after years of searching, they finally found a GI specialist who helped. Grant was diagnosed with Chronic Intestinal Pseudo Obstruction. His symptoms are managed with a combination of medicine and diet.

About half of Grant's food is taken in through a feeding tube. With no cure, and wanting to improve Grant's quality of life, his family hopes and prays that answers will be found through research. And they are taking action.



*Rep. Ed Perlmutter (D-CO-7) with Grant and his mom, Natalie*

### Friends and Family Making a Difference

At year end, Grant's family asked everyone on their holiday card list to help support HR 2239, the Functional GI and Motility Disorders Research Enhancement Act. A description of the journey endured while trying to find effective treatments was sent to friends and family members. They could then reply with a note card that was included, addressed to the Digestive Health Alliance, providing their name and address along with a message of support for HR 2239. We then identified the Congressional representative for everyone who responded and delivered the cards to those representatives' offices. In this way, the family was able to reach representatives beyond their own Congressional district to share Grant's compelling story and raise critical awareness.

Along the way, Grant and his mom, Natalie, have become vocal Digestive Health Advocates, reaching out to and meeting with their own U.S. House of Representatives Member. Thank you, Grant! And thank you to all who advocate and provide support for digestive health.



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: Selena La Porte  
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., and the members of IFFGD. We are grateful for their continued support of IFFGD.

 **Forest Laboratories, Inc.**

  
**Ironwood**

**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](mailto:iffgd@iffgd.org)  
[www.iffgd.org](http://www.iffgd.org)  
[www.aboutconstipation.org](http://www.aboutconstipation.org)  
[www.aboutibs.org](http://www.aboutibs.org)  
[www.aboutincontinence.org](http://www.aboutincontinence.org)  
[www.aboutgerd.org](http://www.aboutgerd.org)  
[www.aboutgimotility.org](http://www.aboutgimotility.org)  
[www.aboutkidsgis.org](http://www.aboutkidsgis.org)  
[www.giresearch.org](http://www.giresearch.org)  
[www.dha.org](http://www.dha.org)