International Foundation for Functional Gastrointestinal Disorde



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Highlights in this issue

Feature Articles

A report from IFFGD research award winner, Ronnie Fass, M.D., looks at the bi-directional relationship of sleep and GERD, and its link with more aggressive symptoms of GERD.

A newly updated overview reviews causes, symptoms, diagnosis, and treatments of gastroparesis, or delayed gastric emptying; from the NIH, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

Research and Treatment News

Researchers have mapped the human microbiome, the normal bacteria that live in and on the healthy human body, setting the stage for better understanding links to health or disease.

Researchers found that functional dyspepsia may lead to sleep loss, and the sleep loss may worsen symptoms.

The FDA is reviewing the new drug application for linaclotide to treat IBS with constipation, and chronic constipation. A decision is expected in late 2012.

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

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

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

A supplemental new drug application has been filed with FDA for lubiprostone to treat opioid-induced constipation in patients with chronic, non-cancer pain.

The FDA is reviewing the new drug application for Gattex to treat short bowel syndrome.

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

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

Community News

IFFGD appeared before the Senate Defense Appropriations Subcommittee to testify about the need to support research for Gulf War Illness.

Digestive Health Alliance advocates visited House and Senate offices in Washington, DC seeking support for federal programs that aim to improve care and find cures for people with functional GI and motility disorders.

Your action is needed to help continue federal budget support for biomedical research, and to make the Functional GI and Motility Disorders Research Enhancement Act law.

Digestive health advocates in action – raising awareness and funds for research.

Report from IFFGD Research Award Winner: Sleep and Gastroesophageal Reflux Disease (GERD)

By: Ronnie Fass, M.D., Professor of Medicine, University of Arizona, Tucson, AZ

Dr. Fass is the recipient of the 2011 IFFGD Research Award for Senior Investigator in Clinical Science. In addition to researching the relationships of sleep with GERD, he is involved in research projects designed to improve understanding, diagnosis, and treatment of nonerosive reflux disease, functional heartburn, noncardiac chest pain, GERD in patients who do not respond to PPI treatment, and several studies in patients with gastroparesis. Other research areas include the role of the brain in generating esophageal-related symptoms, the impact of stroke on patients' symptoms, and a basic science project seeking to determine specific markers in patients with Barrett's esophagus.

Gastroesophageal reflux disease is a chronic disorder and the most common disease that affects the esophagus. Several studies have estimated that 1 in 5 (20%) of the U.S. adult population experience GERD-related symptoms at least once a week. Studies have also demonstrated that up to 4 in 5 (79%) of GERD patients experience nighttime symptoms. Of those patients with nighttime heartburn, three-quarters (75%) reported that the symptoms affected their sleep and nearly half (40%) stated that symptoms impacted their ability to function the following day.

It does appear that GERD and sleep have a bi-directional relationship. GERD has been shown to adversely affect sleep by awakening people from sleep during the night. More commonly, people with GERD experience multiple, short arousals that they are unable to recollect which results in sleep fragmentation. At the same time sleep deprivation, per se, can adversely affect GERD by enhancing perception of acid in the esophagus (esophageal

hypersensitivity), and potentially by increasing esophageal acid exposure time.

The importance of nighttime reflux is related to the fact that this type of reflux is associated

with more aggressive symptoms of GERD (erosive esophagitis or inflammation of the esophagus, complications of GERD, Barrett's esophagus, and cancer of the esophagus). In addition, people with nighttime reflux have a higher prevalence of symptoms in the oral cavities and airways (oropharyngeal, laryngeal and pulmonary manifestations).

Poor quality of sleep and a variety of sleep disturbances have been recently added to the growing list of extraesophageal symptoms of GERD such as hoarseness, throat-clearing, sore throat, wheezing, and chronic cough. Most importantly, the overall quality of life of those with nighttime heartburn appears to be significantly worse than the quality of life of those with daytime heartburn only.

In the last decade, the Neuroenteric Clinical Research Group has been working in the area of GERD and sleep in order to decipher the exact relationship between the two disorders. An advancement that helped us to better understand the impact of GERD on sleep was the incorporation of actigraphy (a watch-like device that can determine if patients are asleep or awake) with their pH test measuring acid exposure matched by time. This combined technique allows us to determine the relationship between gastroesophageal reflux events, symptoms, and sleep and awake periods.

In a series of studies that we performed and subsequently published, we have been able to demonstrate that the time spent in bed prior to falling asleep is a vulnerable period for gastroesophageal reflux to occur. The longer the time spent awake in bed the greater the esophageal acid exposure experienced.

In addition, we were able to demonstrate that during sleep people with GERD woke up multiple times. However, only one-half (50%) of the awakenings were associated with gastroesophageal reflux. Surprisingly, most of the gastroesophageal reflux related awakenings were not associated with symptoms, suggesting that those with GERD may wake up from sleep during the night with a significant reflux but without symptoms.

We were also able to demonstrate that most acid reflux events during sleep occur after the person awoke from sleep. Furthermore, we were also able to demonstrate that waking up in the morning is also associated with a significant reflux. In other words, transitioning from sleep to awake in the morning is associated with significant reflux in those with GERD. Sleep, especially deep sleep, has been shown in our studies to be

suppressive of gastroesophageal reflux.

One of the conclusions of our studies was the importance of minimizing the time people with GERD spend in bed awake. As a result,

we recently embarked on a study where we assessed the value of a prescription drug that promotes falling asleep, ramelteon (a melatonin receptor agonist), on gastroesophageal reflux related symptoms during sleep. People with GERD received only ramelteon prior to going to sleep during a period of 6 weeks; a comparative group was treated with placebo. The study demonstrated that those who received ramelteon at bedtime for 6 weeks reported significantly less GERD related symptoms during nighttime. The effect was mediated by improving sleep quality, as documented by a questionnaire.

In another recent study, we evaluated the role of naps in bringing about gastroesophageal reflux. Naps are associated with more shallow sleep, which is much more vulnerable for gastroesophageal reflux to occur. The combination of taking a nap after a meal may result in more severe gastroesophageal reflux disease.

"Nighttime reflux is associated with more aggressive symptoms of GERD."



Report Cont.

Our study demonstrated that naps were much more commonly associated with gastroesophageal reflux, as well as GERD related symptoms, when compared with an equivalent sleep time during the nighttime.

Our future direction is to further explore if medications that improve sleep can be an asset for people with GERD that have symptoms during sleep. In particular, our focus will be on combination therapy of an antireflux treatment plus a sleeping pill, like a melatonin receptor agonist, in improving GERD related symptoms.

Healthy Sleep

Getting enough good sleep is important for everyone, but it is especially important for those living with chronic disorders such as functional gastrointestinal (GI) and motility disorders. Lack of quality sleep can impact your digestive symptoms. Conversely, symptoms of GI disorders can also impact the quality of your sleep. To understand why sleep is important, it is helpful to know a little background on the science of sleep. It is also helpful to know how you can improve your sleep habits.

Different Stages of Sleep

A sleep cycle goes through stages that consist of two basic states: non-rapid eye movement (NREM, stages 1–4) and rapid eye movement (REM, stage 5) sleep. Each stage of the cycle is vital to getting a good night's rest.

Stage 1

- o This is a brief stage a sleep between being awake and fully asleep. This stage is characterized by slowed muscle activity.
- Stage 2
 - o The second stage of sleep is when the body temperature drops, brain waves become slower, and the breathing and heart rate stay regular.
- Stage 3–4
 - o The most restorative sleep occurs during these stages. The breathing slows down, the blood pressure drops, and activity stops in the muscles. Energy is restored and repair to tissue occurs. Hormones for growth and development are also released in this stage.

• Stage 5

o The only stage of REM sleep is stage 5. Breathing becomes rapid and irregular. The heart rate increases and the blood pressure rises. This stage gives energy to the body and the brain as the muscles are even more relaxed. It is in this stage that dreams occur. Studies also suggest that REM sleep stimulates the part of the brain used for learning and memory.

Effects of Sleep

Sleep is important to your physical, mental, and emotional well-being. Some of the positive effects of sleep include:

- Thinking clearly
- Reacting quickly
- Creating memories
- Focusing on specific tasks
- Building of muscle mass
- Repairing cells and tissue
- Releasing hormones that help the immune system fight infection
- Controlling the body's use of energy
- Coping with pain

Tips for Improving Your Sleep Habits

If you struggle with getting a good night's rest, here are some simple tips to improve your sleep quality. Should you continue to have trouble sleeping or if you do not feel well rested during the day despite being in bed at night, you may want to speak to your doctor.

- Stick to a sleep schedule. Go to bed and wake up at a regular time *(even on weekends)*.
- Exercise. Include regular exercise into your schedule.
- Avoid caffeine and nicotine. It can take 8 hours for the effects of caffeine to wear off.
- Avoid alcohol before bed. Alcohol keeps you in the lighter stages of sleep.
- Avoid large meals and beverages late at night. This can cause reflux as well as cause you to awaken frequently to use the bathroom.
- Avoid naps after eating, it can cause reflux.
- Don't take naps after 3 pm. It might interfere with your ability to fall asleep.
- Relax before bed. This should be a daily part of your sleep ritual.
- Have a good sleeping environment. Get rid of anything that might distract or interrupt your sleep such as TVs, computers, bright lights, or noises.
- Don't lie awake in bed. If you are awake in bed for more than 20 minutes, get up and do a relaxing activity until you feel sleepy.

Research News You Can Use

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

The Human Microbiome in Health and Disease

(June 2012) The National Institutes of Health (NIH) reported that researchers have mapped the normal bacteria that live in and on the healthy human body. The accomplishment sets the stage for better understanding how bacterial communities affect human health and disease.

The human body is host to trillions of microbes. These microbes outnumber the body's cells by 10 to 1. Most of the time they are beneficial to human health, but sometimes they can cause illness. Scientists are using new genomic techniques to study these microbial communities and their genes, which collectively are known as the microbiome.

The Human Microbiome Project (HMP) was launched by NIH in 2007 to characterize the microbes found in different regions of the body, including the digestive tract. The scientists studied the microbes of 242 healthy adult volunteers by collecting tissue from 15 body sites in men and 18 in women. The scientists found that more than 10,000 microbial species occupy the human body. They estimated that the microbiome provides more genes that contribute to human survival than the human genome itself provides (8 million vs. 22,000). Humans need bacterial genes to aid in basic processes such as digestion.

"Enabling disease-specific studies is the whole point of the Human Microbiome Project," says Dr. Barbara Methé of the J. Craig Venter Institute. "Now that we understand what the normal human microbiome looks like, we should be able to understand how changes in the microbiome are associated with, or even cause, illnesses."

Source: National Institutes of Health (NIH). NIH Research Matters web page: nih.gov/researchmatters/ june2012/06252012microbiome.htm (Accessed June 25, 2012)

Functional Dyspepsia and Sleep

A study by Lacy and colleagues found that functional dyspepsia (FD) is associated with sleep disturbances and lower sleep quality. Sleep disturbances, such as trouble falling asleep and early awakening, may have an effect on physical as well as emotional well-being.

This may be a bi-directional relationship. In other words, people with FD may suffer from disordered sleep due to their symptoms, and the sleep loss may worsen their symptoms. Functional dyspepsia is a chronic gastrointestinal disorder characterized by upper abdominal pain or discomfort. Symptoms frequently include burning, pressure, or fullness, which often, but not necessarily, are related to meals. Other common symptoms include early feeling of fullness (satiety), nausea, belching, and bloating.

The researchers analyzed questionnaires from 131 people with FD. Fifty people without FD were also surveyed to serve as a control. The results show that people with FD spent more time than people without in getting to sleep. Forty-three percent of those with FD had trouble falling asleep while 64% reported trouble staying asleep (Compared to 28% and 36% respectively in the control group). Additionally, Lacy noted that the more severe the FD symptom, the more likely the person was to report a sleep disturbance.

In total, 70% of people with FD reported having problems falling or staying asleep. This lack of quality sleep reduces the ability of the body to cope with pain.

Source: Lacy BE, Everhart K, Crowell, MD. Functional dyspepsia is associated with sleep disorders. *Clinical Gastroenterology and Hepatology* 2011 May; 9(5):410-414.

Clinical Trials Pave the Way for New Treatments

Would you like to play a more active role in your own health care, learn more about your condition and how to manage it, and help yourself and others by contributing to medical research? Consider taking part in a clinical trial (also called a clinical study).

In general, a clinical trial is a biomedical or health-related research study in people that follows a pre-defined protocol. Through these research studies, investigators find new and better ways to treat, control, prevent, diagnose, or detect conditions, or to improve the quality of life for those with an illness. Trials can take place in a variety of locations, such as hospitals, universities, doctors' offices, or community clinics.

A protocol is a study plan carefully designed to safeguard the health of the participants as well as answer specific research questions. A protocol describes what types of people may participate in the trial; the schedule of tests, procedures, medications, and dosages; and the length of the study. While in a clinical trial, participants following a protocol are seen regularly by the research staff to monitor their health and to determine the safety and effectiveness of their treatment. While efforts are made to control risks to clinical trial participants, some risk may be unavoidable because of the uncertainty inherent in clinical research involving new medical products. It's important, therefore, that decisions to participate in a clinical trial are made only after obtaining a full understanding of the entire process and the risks that may be involved.

Choosing to participate in a clinical trial is an important personal decision. It is often helpful to talk to a physician, family members, or friends about deciding to join a trial. General information about clinical trials can be found at the IFFGD web page at *www.giResearch.org/site/gi-research/ studies/guide* or at the National Institutes of Health web site at *www.clinicaltrials.gov*, among others.

After identifying a trial of interest to you, the next step is to contact the study research staff and ask questions about specific trials. Here is a list of several studies which are currently seeking participants.

A Phase 3 Study of a new Medication for the Treatment of Patients with Diarrhea-Predominant Irritable Bowel Syndrome (IBS-D)

Purpose of the study: To evaluate the efficacy, safety, and tolerability of JNJ-27018966 compared with placebo in the treatment of patients with irritable bowel syndrome (IBS) with the subtype of diarrhea.

Sponsored by: Furiex Pharmaceuticals, Inc.

Participation: Eligible male and female patients aged 18 to 80 years with a diagnosis of irritable bowel syndrome (IBS) with a subtype of diarrhea.

For information call: 1-877-345-2145

Genetic Analysis of Hirschsprung's Disease

Purpose of the study: Understanding the genetics of Hirschsprung's disease with the further goal of improving diagnosis, treatment, and genetic counseling.

Sponsored by: National Institutes of Health (NIH), Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

Participation: The study population includes individuals with Hirschsprung's disease and their family members.

For information contact the study coordinator: Courtney Berrios, at 410-502-7541 or hirschsprung@igm.jhmi.edu

Antidepressant Therapy for Functional Dyspepsia

Purpose of the study: To investigate whether antidepressant medications are efficacious in treating functional dyspepsia, including psychological benefits, reduced pain, and altered motility.

Sponsored by: Mayo Clinic in collaboration with NIH, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) **Participation:** Eligible males and females age 18 to 75 years.

For information contact the study coordinator: Katherine E Tilkes at 877-825-8999, or tilkes.katherine@mayo.edu.

Gastroparesis – An Overview

Source: NIH Publication No. 12-4348, June 2012. This publication is not copyrighted.

What is gastroparesis?

Gastroparesis, also called delayed gastric emptying, is a disorder that slows or stops the movement of food from the stomach to the small intestine. Normally, the muscles of the stomach, which are controlled by the vagus nerve, contract to break up food and move it through the gastrointestinal (GI) tract. The GI tract is a series of hollow organs joined in a long, twisting tube from the mouth to the anus. The movement of muscles in the GI tract, along with the release of hormones and enzymes, allows for the digestion of food. Gastroparesis can occur when the vagus nerve is damaged by illness or injury and the stomach muscles stop working normally. Food then moves slowly from the stomach to the small intestine or stops moving altogether.

What causes gastroparesis?

Most people diagnosed with gastroparesis have idiopathic gastroparesis, which means a health care provider cannot identify the cause, even with medical tests. Diabetes is the most common known cause of gastroparesis. People with diabetes have high levels of blood glucose, also called blood sugar. Over time, high blood glucose levels can damage the vagus nerve. Other identifiable causes of gastroparesis include intestinal surgery and nervous system diseases such as Parkinson's disease or multiple sclerosis. For reasons that are still unclear, gastroparesis is more commonly found in women than in men.

What are the symptoms of gastroparesis?

The most common symptoms of gastroparesis are nausea, a feeling of fullness after eating only a small amount of food, and vomiting undigested food – sometimes several hours after a meal. Other symptoms of gastroparesis include

- gastroesophageal reflux (GER), also called acid reflux or acid regurgitation a condition in which stomach contents flow back up into the esophagus, the organ that connects the mouth to the stomach
- pain in the stomach area
- abdominal bloating
- lack of appetite

Symptoms may be aggravated by eating greasy or rich foods, large quantities of foods with fiber – such as raw fruits and vegetables – or drinking beverages high in fat or carbonation. Symptoms may be mild or severe, and they can occur frequently in some people and less often in others. The symptoms of gastroparesis may also vary in intensity over time in the same individual. Sometimes gastroparesis is difficult to diagnose because people experience a range of symptoms similar to those of other diseases.

How is gastroparesis diagnosed?

Gastroparesis is diagnosed through a physical exam, medical history, blood tests, tests to rule out blockage or structural problems in the GI tract, and gastric emptying tests. Tests may also identify a nutritional disorder or underlying disease. To rule out any blockage or other structural problems, the health care provider may perform one or more of the following tests:

Upper gastrointestinal (GI) endoscopy – This procedure involves using an endoscope -a small, flexible tube with a light – to see the upper GI tract, which includes the esophagus. stomach, and duodenum – the first part of the small intestine. The test is performed at a hospital or outpatient center by a gastroenterologist -a doctor who specializes in digestive diseases. The endoscope is carefully fed down the esophagus and into the stomach and duodenum. A small camera mounted on the endoscope transmits a video image to a monitor, allowing close examination of the intestinal lining. A person may receive a liquid anesthetic that is gargled or sprayed on the back of the throat. An intravenous (IV) needle is placed in a vein in the arm if general anesthesia is given. The test may show blockage or large bezoars - solid collections of food, mucus, vegetable fiber, hair, or other material that cannot be digested in the stomach – that are sometimes softened, dissolved, or broken up during an upper GI endoscopy.

Upper GI Series – An upper GI series may be done to look at the small intestine. The test is performed at a hospital or outpatient center by an x-ray technician, and the images are interpreted by a radiologist – a doctor who specializes in medical imaging. Anesthesia is not needed. No eating or drinking is allowed for 8 hours before the procedure, if possible. If the person has diabetes, a health care provider may give different instructions about fasting before the test. During the procedure, the person will stand or sit in front of an x-ray machine and drink barium, a chalky liquid. Barium coats the small intestine, making signs of gastroparesis show up more clearly on x-rays. Gastroparesis is likely if the x-ray shows food in the stomach after fasting. A person may experience bloating and nausea for a short time after the test. For several days afterward, barium liquid in the GI tract causes stools to be white or light colored. A health care provider will give the person specific instructions about eating and drinking after the test.

Ultrasound – Ultrasound uses a device, called a transducer, that bounces safe, painless sound waves off organs to create an image of their structure. The procedure is performed in a health care provider's office, outpatient center, or hospital by a specially trained technician, and the images are interpreted by a radiologist; anesthesia is not needed. The images can show whether gallbladder disease and pancreatitis could be the cause of a person's digestive symptoms, rather than gastroparesis.

Gastric Emptying Scintigraphy – The test involves eating a bland meal – such as eggs or an egg substitute – that contains a small amount of radioactive material. The test is performed in a radiology center or hospital by a specially trained technician and interpreted by a radiologist; anesthesia is not needed. An external camera scans the abdomen to show where the radioactive material is located. The radiologist is then able to measure the rate of gastric emptying at 1, 2, 3, and 4 hours after the meal. If more than 10 percent of the meal is still in the stomach at 4 hours, the diagnosis of gastroparesis is confirmed.

SmartPill – The SmartPill is a small electronic device in capsule form. The SmartPill test is available at specialized outpatient centers. The images are interpreted by a radiologist. The device is swallowed and moves through the entire digestive tract, sending information to a cell-phone-sized receiver worn around the person's waist or neck. The recorded information provides a detailed record of how quickly food travels through each part of the digestive tract.

Breath Test – With this test, the person eats a meal containing a small amount of radioactive material; then breath samples are taken over a period of several hours to measure the amount of radioactive material in the exhaled breath. The results allow the health care provider to calculate how fast the stomach is emptying.

How is gastroparesis treated?

Treatment of gastroparesis depends on the severity of the person's symptoms. In most cases, treatment does not cure gastroparesis, which is usually a chronic, or long-lasting, condition. Gastroparesis is also a relapsing condition – the symptoms can come and go for periods of time. Treatment helps people manage the condition so they can be as comfortable and active as possible.

Eating, Diet, and Nutrition – Changing eating habits can sometimes help control the severity of gastroparesis symptoms. A health care provider may suggest eating six small meals a day instead of three large ones. If less food enters the stomach each time a person eats, the stomach may not become overly full, allowing it to empty more easily. Chewing food well, drinking noncarbonated liquids with a meal, and walking or sitting for 2 hours after a meal – instead of lying down – may assist with gastric emptying.

A health care provider may also recommend avoiding high-fat and fibrous foods. Fat naturally slows digestion and some raw vegetables and fruits are more difficult to digest than other foods. Some foods, such as oranges and broccoli, contain fibrous parts that do not digest well. People with gastroparesis should minimize their intake of large portions of these foods because the undigested parts may remain in the stomach too long. Sometimes, the undigested parts form bezoars.

When a person has severe symptoms, a liquid or puréed diet may be prescribed. As liquids tend to empty more quickly from the stomach, some people may find a puréed diet helps improve symptoms. Puréed fresh or cooked fruits and vegetables can be incorporated into shakes and soups. A health care provider may recommend a dietitian to help a person plan meals that minimize symptoms and ensure all nutritional needs are met.

When the most extreme cases of gastroparesis lead to severe nausea, vomiting, and dehydration, urgent care may be required at a medical facility where IV fluids can be given.

Medications – Several prescription medications are available to treat gastroparesis. A combination of medications may be used to find the most effective treatment.

- Metoclopramide (Reglan). This medication stimulates stomach muscle contractions to help with gastric emptying. Metoclopramide also helps reduce nausea and vomiting. The medication is taken 20 to 30 minutes before meals and at bedtime. Possible side effects of metoclopramide include fatigue, sleepiness, and depression. Currently, this is the only medication approved by the FDA for treatment of gastroparesis. However, the FDA has placed a black box warning on this medication because of rare reports of it causing an irreversible neurologic side effect called tardive dyskinesia – a disorder that affects movement. [Important Safety Note: Be sure to understand this risk and stay in touch with your doctor if you are prescribed this drug. Tardive dyskinesia is a serious movement disorder. The risk of developing tardive dyskinesia increases with the duration of treatment and the total cumulative dose. The FDA warns that treatment with metoclopramide (Reglan) for longer than 12 weeks should be avoided in all but rare cases where therapeutic benefit is thought to outweigh the risk of developing tardive dyskinesia.]
- Erythromycin. This antibiotic, prescribed at low doses, may improve gastric emptying. Like metoclopramide, erythromycin works by increasing the contractions that move food through the stomach. Possible side effects of erythromycin include nausea, vomiting, and abdominal cramps.
- Other medications. Other medications may be used to treat symptoms and problems related to gastroparesis. For example, medications known as antiemetics are used to help control nausea and vomiting.

Botulinum Toxin – Botulinum toxin is a nerve blocking agent also known as Botox. After passing an endoscope into the stomach, a health care provider injects the Botox into the pylorus, the opening from the stomach into the duodenum. Botox is supposed to help keep the pylorus open for longer periods of time and improve symptoms of gastroparesis. Although some initial research trials showed modest improvement in gastroparesis symptoms and the rate of gastric emptying following the injections, other studies have failed to show the same degree of effectiveness of the Botox injections. (Bai Y, Xu MJ, Yang X, et al. A systematic review on intrapyloric botulinum toxin injection for gastroparesis. Digestion. 2010;81(1):27–34.)

Gastric Electrical Stimulation – This treatment alternative may be effective for some people whose nausea and vomiting do not improve with dietary changes or medications. A gastric neurostimulator is a surgically implanted battery-operated device that sends mild electrical pulses to the stomach muscles to help control nausea and vomiting. The procedure may be performed at a hospital or outpatient center by a gastroenterologist. General anesthesia may be required. The gastroenterologist makes several tiny incisions in the abdomen and inserts a laparoscope – a thin tube with a tiny video camera attached. The camera sends a magnified image from inside the stomach to a video monitor, giving the gastroenterologist a close-up view of the tissues. Once implanted, the settings on the battery-operated device can be adjusted to determine the settings that best control symptoms.

Jejunostomy – If medications and dietary changes don't work, and the person is losing weight or requires frequent hospitalization for dehydration, a health care provider may recommend surgically placing a feeding tube through the abdominal wall directly into a part of the small intestine called the jejunum. The surgical procedure is known as a jejunostomy. The procedure is performed by a surgeon at a hospital or outpatient center. Anesthesia is needed. The feeding tube bypasses the stomach and delivers a special liquid food with nutrients directly into the jejunum. The jejunostomy is used only when gastroparesis is extremely severe.

Parenteral Nutrition – When gastroparesis is so severe that dietary measures and other treatments are not helping, a health care provider may recommend parenteral nutrition – an IV liquid food mixture supplied through a special tube in the chest. The procedure is performed by a surgeon at a hospital or outpatient center; anesthesia is needed. The surgeon inserts a thin, flexible tube called a catheter into a chest vein, with the catheter opening outside the skin. A bag containing liquid nutrients is attached to the catheter, and the nutrients are transported through the catheter into the chest vein and into the bloodstream. This approach is a less preferable alternative to a jejunostomy and is usually a temporary treatment to get through a difficult period of gastroparesis.

How is gastroparesis treated if a person has diabetes?

An elevated blood glucose level directly interferes with normal stomach emptying, so good blood glucose control in people with diabetes is important. However, gastroparesis can make blood glucose control difficult. When food that has been delayed in the stomach finally enters the small intestine and is absorbed, blood glucose levels rise. Gastric emptying is unpredictable with gastroparesis, causing a person's blood glucose levels to be erratic and difficult to control. The primary treatment goals for gastroparesis related to diabetes are to improve gastric emptying and regain control of blood glucose levels. In addition to the dietary changes and treatments already described, a health care provider will likely adjust the person's insulin regimen.

To better control blood glucose, people with diabetes and gastroparesis may need to:

- take insulin more often or change the type of insulin they take
- take insulin after meals, instead of before
- check blood glucose levels frequently after eating and administer insulin when necessary

A health care provider will give specific instructions for taking insulin based on the individual's needs and the severity of gastroparesis.

In some cases, the dietitian may suggest eating several liquid or puréed meals a day until gastroparesis symptoms improve and blood glucose levels are more stable.

What are the problems of gastroparesis?

The problems of gastroparesis can include:

- severe dehydration due to persistent vomiting
- gastroesophageal reflux disease (GERD), which is GER that occurs more than twice a week for a few weeks; GERD can lead to esophagitis – irritation of the esophagus
- bezoars, which can cause nausea, vomiting, obstruction, or interfere with absorption of some medications in pill form
- difficulty managing blood glucose levels in people with diabetes
- malnutrition due to poor absorption of nutrients or a low calorie intake
- decreased quality of life, including work absences due to severe symptoms

Points to Remember

- Gastroparesis, also called delayed gastric emptying, is a disorder that slows or stops the movement of food from the stomach to the small intestine.
- Gastroparesis can occur when the vagus nerve is damaged by illness or injury and the stomach muscles stop working normally. Food then moves slowly from the stomach to the small intestine or stops moving altogether.
- Most people diagnosed with gastroparesis have idiopathic gastroparesis, which means a health care provider cannot identify the cause, even with medical tests.

- Diabetes is the most common known cause of gastroparesis. People with diabetes have high levels of blood glucose, also called blood sugar. Over time, high blood glucose levels can damage the vagus nerve.
- The most common symptoms of gastroparesis are nausea, a feeling of fullness after eating only a small amount of food, and vomiting undigested food – sometimes several hours after a meal. Other common symptoms include gastroesophageal reflux (GER), pain in the stomach area, abdominal bloating, and lack of appetite.
- Gastroparesis is diagnosed through a physical exam, medical history, blood tests, tests to rule out blockage or structural problems in the gastrointestinal (GI) tract, and gastric emptying tests.
- Changing eating habits can sometimes help control the severity of gastroparesis symptoms. A health care provider may suggest eating six small meals a day instead of three large ones. When a person has severe symptoms, a liquid or puréed diet may be prescribed.
- Treatment of gastroparesis may include medications, botulinum toxin, gastric electrical stimulation, jejunostomy, and parenteral nutrition.
- For people with gastroparesis and diabetes, a health care provider will likely adjust the person's insulin regimen.

Hope through Research

The National Institute of Diabetes and Digestive and Kidney Diseases' (NIDDK's) Division of Digestive Diseases and Nutrition supports basic and clinical research into GI motility disorders, including gastroparesis. Researchers are studying whether new medications or surgery can improve gastric emptying and reduce gastroparesis symptoms.

Acknowledgments

This is a publication of the National Digestive Diseases Information Clearinghouse (NDDIC), a service of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The NIDDK is part of the National Institutes of Health (NIH) of the U.S. Department of Health and Human Services. Publications produced by the Clearinghouse are carefully reviewed by both NIDDK scientists and outside experts. This publication was reviewed by Linda A. Lee, M.D., Johns Hopkins University School of Medicine.

Notes:

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 AuthorCrystal 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 patientadvocate 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

AuthorRobert 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

AuthorCrystal 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.

Title: Understanding the Irritable Gut: The Functional Gastrointestinal Disorders Author:W. Grant Thompson, M.D. Publisher:Degnon Associates (2008) Pages:240 (paperback)The functional gastrointestinal (GI) disorders can perplex doctors and patients alike. This book seeks to demystify these disorders. Dr. Thompson explains with ease and clarity the nature, prevalence, and possible causes of these disorders. The information developed and assembled by the Rome Foundation to identify, classify, and treat these disorders is presented in an easy-to-read, nontechnical format. Available online at: www.theromefoundation.org.

Title:Noncardiac Chest Pain: A Growing Medical Problem Editors:Ronnie Fass, M.D., Guy D. Eslick, Ph.D.

Publisher: Plural Publishing, Inc. (2007) Pages:188 (hardcover)

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

Title: Controlling IBS the Drug-Free Way: A 10-Step Plan for Symptom Relief Author: Jeffrey M. Lackner, Psy.D. Publisher: STC Healthy Living (2007) Pages:256 (paperback) The book offers a step-by-step self-management approach that anyone with IBS can easily follow to reduce symptoms without drugs or professional help. Also included are up-to-date overviews of medications and dietary strategies that readers can use to help with symptom control. Dr. Lackner is director of the Behavioral Medicine Clinic and Assistant Professor in the Department of Medicine at the State University of New York at Buffalo School of Medicine. Available through booksellers.

Title: Rome III: The Functional Gastrointestinal Disorders Senior Editor: Douglas A. Drossman, M.D. Publisher: Degnon Associates (2006) Pages:1,048 pages (hardcover) Five years in the making, Rome III is designed for "one stop" learning for health professionals. Rome III provides the most up-to-date information on the epidemiology, pathophysiology, diagnosis, and treatment of irritable bowel syndrome and over 20 more functional GI disorders commonly seen in clinical practice. This third edition is expanded with 17 chapters to address the needs of both investigators and clinicians. New chapters include pharmacology and pharmacokinetics, sociocultural influences relating to gender, age, and cultural influences, functional abdominal pain, and two chapters on pediatrics for the neonate/toddler and child/ adolescent.

Available online at: www.theromefoundation.org.

IFFGD INDUSTRY COUNCIL

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

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

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

IFFGD INDUSTRY COUNCIL

Sucampo Pharmaceuticals, Inc. and Takeda Pharmaceuticals USA, Inc. Salix Pharmaceuticals, Ltd. 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 nonconstipation 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, placebocontrolled 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.

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.

Lubiprostone Results Positive in Treating Opioid-Induced Bowel Dysfunction

On July 26, 2012 Sucampo Pharmaceuticals, Inc. and Takeda Pharmaceuticals USA., Inc. announced that Sucampo Pharmaceuticals announced the filing of a supplemental new drug application (sNDA) with the U.S. Food and Drug Administration (FDA) seeking approval for a new indication for lubiprostone for the treatment of opioidinduced constipation (OIC) in patients with chronic, non-cancer pain.

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 opioidbased medications. The most common symptom is constipation. Others symptoms may include decreased gastric emptying, abdominal cramping, spasm, bloating, and delayed GI transit.

The phase 3, randomized, placebocontrolled, 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.

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 glucagonlike 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.

Phase 3 Clinical Trials Begin for new Treatment of Diarrhea-Predominant Irritable Bowel Syndrome

MuDelta (JNJ-27018966) 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.

Phase 3 Clinical Trial

(June 15, 2012) Recruitment of male and female adult patients has started for the Phase 3 clinical study of this drug. The purpose of Phase 3 studies is to look at effectiveness, monitor side effects, and collect information that will allow the drug or treatment to be used safely.

Purpose of the study: To evaluate the efficacy, safety, and tolerability of JNJ-27018966 compared with placebo in the treatment of patients with irritable bowel syndrome (IBS) with the subtype of diarrhea.

Participation: Eligible male and female patients aged 18 to 80 years with a diagnosis of irritable bowel syndrome (IBS) with a subtype of diarrhea.

Sponsored by: Furiex Pharmaceuticals

For information call: 1-877-345-2145

A completed Phase 2 proof-of-concept clinical trial evaluated the safety and efficacy of MuDelta (JNJ-27018966). 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, doubleblind, 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.

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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 accumulate data that further evaluates the drug's safety and effectiveness. Furiex Pharmaceuticals, Inc. is developing the drug under a November 2009 development and license agreement with Janssen Pharmaceutica N.V.

Professional Announcements

Save the Date - IFFGD Professional Symposium

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

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

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

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

For further information, contact:

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

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



Scan this code with your smart phone for more informaton.

Behavioral and Rehabilitation Treatment of Bowel Disorders: An Advanced Course

This course will be presented **Sept 27–29, 2012** at Marquette University in **Milwaukee**, **Wisconsin**. This is the 4th annual offering of this course, and it has been expanded to 3 days.

This is an advanced course designed for nurses, physical therapists, occupational therapists and other health care providers who are seeking a better understanding of the various bowel disorders that affect children, women and men; and the specific rehabilitation strategies that are useful in treating these disorders. This course is appropriate for providers who have already attended a basic didactic course that has covered rehabilitation and biofeedback treatment for pelvic floor disorders. Please visit *www. marquette.edu/cbs/continuing_ed.shtml* and click on the course title for more information.

Contact: Please email diane.slaughter@marquette.edu

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*.

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 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 Web: www.giresearch.org/awards



Scan this code with your smart phone for more informaton.



Community News



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

Taking Action for Digestive Health

IFFGD and Digestive Health Alliance advocates have been busy on Capitol Hill this summer. We have been working to improve the lives of everyone affected by a functional GI/motility disorder.

IFFGD testified on June 6, 2012 before the Senate Appropriations Subcommittee on Defense. We asked for support of the Gulf War Illness Research Program, explaining the need to help the high number of veterans returning with functional GI disorders.

Advocates from around the country travelled to Washington on June 19–20, 2012 for DHA Advocacy Day 2012. They visited Congressional offices to educate their representatives about functional GI and motility disorders (FGIMDs) and ask for their support of federal research and education programs aimed at improving care and finding cures for people with these disorders. During the prior week, many more advocates participated in a Digestive Health Congressional Call-in Day asking Members of Congress to support *The Functional GI & Motility Disorders Research Enhancement Act of 2011 (H.R. 2239).*

As a result of these combined efforts, the needs of the FGIMD community is increasingly being heard and understood by legislators. Add your voice – go to our web page at *www.iffgd.org/* action to take part. Or email us at *dha@iffgd.org* to share your concerns and learn more about how you can help.

Senate Defense Appropriations Subcommittee Testimony

For the last two years, IFFGD has been called before the Senate Defense Appropriations Subcommittee to testify on the issue of functional GI disorders and their impact on military personnel. This Subcommittee is currently crafting the Fiscal Year (FY) 2013 Defense Appropriations Bill, and Senators are considering continued support for the Gulf War Illness Research Program through the DOD Peer-Reviewed Medical Research Program, which includes "functional GI disorders" on the list of conditions eligible for study. The DOD research program is intended to only fund research into conditions that disproportionately impact military personnel or are related to military service.

IFFGD Testimony – Chairman Inoyue, Vice Chairman Cochran, and distinguished members of the Subcommittee, thank you for the opportunity to present testimony regarding functional gastrointestinal disorders (FGIDs) among service personnel and veterans. My name is Elisabeth Vink and I am testifying on behalf of the International Foundation for Functional Gastrointestinal Disorders, or IFFGD. IFFGD is a nonprofit organization dedicated to supporting individuals affected by functional gastrointestinal and motility disorders through education and research. I am also a proud member of a military family, with my father having served 23 years in the U.S. Air Force, and I appreciate the opportunity to present testimony in support of veterans like my dad.



Elisabeth Vink gives testimony

FGIDs are disorders in which the movement of the intestines, the sensitivity of the nerves of the intestines, or the way in which the brain controls intestinal function is impaired. The result is multiple, persistent, and often painful symptoms ranging from nausea and vomiting to altered bowel habit. Over two dozen different FGIDs have been identified, ranging in severity from bothersome to disabling. One thing these conditions have in common is that little is understood about their underlying mechanisms, making them difficult to treat effectively.

The onset of a functional GI disorder can be triggered by severe stress and infections of the digestive system. Deployed military personnel face an elevated chance of experiencing these risk factors and developing FGIDs as a result of their service. For this reason, continued research through the Department of Defense Gulf War Illness Research Program is critical in FY13. In 2010, the Institute of Medicine published a report titled Gulf War and Health, Volume 8: Update on the Health Effects of Serving in the Gulf War, which determined that there is sufficient evidence to associate deployment to the Gulf War and FGIDs. According to the report, there have been a large number of FGID cases among Gulf War veterans, and their symptoms have continued in the years since the war.

Based on the report from IOM, the VA adopted a final rule on in August 2011 stating that there is a presumptive service connection between FGIDs and service in the Southwest Asia Theater of Operations during the Persian Gulf War.

Our military personnel are taught to put duty first, and we have noticed that by the time they reach out to us, their condition is incredibly painful or highly disruptive to their life. Not only are these disorders hard to treat, but in the words of one retired just as hard to talk about. In order to better articulate the suffering associated with FGIDs, I would like to share with you the voices of veterans affected by these disorders. This is from Stephen in North Carolina who served in the Persian Gulf Theater of Operations:

"While there, and since my return, I have been plagued with a multitude of GI problems including IBS...I suffered nearly constant diarrhea for over ten years before the IBS was ever diagnosed. None of my GI problems existed prior to my deployment and they simply do not seem to go away afterwards."

Another veteran, Jason, mentioned the prevalence of these conditions:

"While speaking with several of my former soldiers I came to realize that they are experiencing the same signs and symptoms. I am the first one of a group of friends/vets that is doing research to find out that we are not alone."

The DOD Gulf War Illness Research Program conducts important research on the complex set of chronic symptoms that impact Gulf War Veterans. Given the conclusions of the IOM report and the report's recommendations for further research on the link between FGIDs and exposures experienced by veterans in the Gulf War, we ask that you continue to support the Gulf War Illness Research Program and encourage research into FGIDs through this program so that important research on FGIDs among veterans can be conducted.

Thank you for your time and your consideration of this request.

DHA Advocacy Day 2012

The 2012 DHA Advocacy Day took place June 19–20, 2012 in Washington, DC. Digestive Health Alliance advocates from across the country gathered in the nation's capital for the annual, twoday event to educate Members of Congress about the needs of the functional gastrointestinal and motility disorders (FGIMDs) community.

A networking dinner on Tuesday evening featured an update on federal research at the National Institutes of Health by Stephen James, M.D., Director, Division of Digestive Diseases and Nutrition, NIDDK, and a review of the 2012 DHA legislative agenda.



DHA Advocates on Capitol Hill

Visiting Congressional Offices

On Wednesday, advocates visited nearly 40 offices meeting with House and Senate staff and Members of Congress to urge support for a legislative agenda focused on bolstering research into functional gastrointestinal and motility disorders and improving patient care. The digestive health advocates represented many different disorders. They shared their personal stories in urging Members of Congress to take action on 3 specific and critical issues:

- House Member co-sponsorship of **The Functional Gastrointestinal and Motility Disorders Research Enhancement Act of 2011 (H.R. 2239)** and the introduction of a companion bill in the Senate
- Support of **increased funding for the National Institutes of Health (NIH)** to a level of at least \$32 billion in Fiscal Year 2013
- **Support for veterans** in the FY13 Defense Appropriations bill through the Department of Defense Peer-Reviewed Gulf War Illness Research Program, which provides a source of funding for functional GI disorders research





DHA Advocates meet with Oklahoma Rep. Dan Boren



DHA Advocate meet with Wisconsin Rep. Paul Ryan

Holding a Briefing

The day concluded with a briefing we sponsored for congressional staff members where many more offices also learned about functional GI and motility disorders. The briefing featured testimony from a practicing physician and two people who live with digestive conditions.

Elisabeth Vink from IFFGD/DHA and Albena Halpert, M.D., Asst. Professor of Medicine at Boston University School of Medicine described the widespread and complex nature of these disorders, their social and economic costs, the lack of satisfactory treatments, and the need for expanded research. Reneé Pickle, who suffers from IBS and GERD; and Hollie Moots, who suffers from gastroparesis, described in compelling everyday terms the challenges and burdens of living with chronic FGIMDs.

During the discussion that followed, several other advocates, as well as some Congressional staff members, shared personal experiences of living with a FGIMD and supporting the need for improved care.



You Can Help

Please add your voice. You can tell your story and ask your House Member to support the **Functional Gastrointestinal and Motility Disorders Research Enhancement Act of 2011 (H.R. 2239)** by going to our web page at *www.iffgd.org/2239action*. It only takes a minute or two to make a big difference.

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 and impactful email to your House Member urging support of H.R. 2239 online at *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!**

Panel Members

Community News Cont.

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

To date, these House Members have cosponsored the bill:

Rep. F. James Sensenbrenner, Jr. (R-WI-5) Rep. James Moran (D-VA-8) Rep. Peter Welch (D-VT) Rep. Elton Gallegly (R-CA-24) Rep. Jesse Jackson, Jr. (D-IL-2) Rep. Tammy Baldwin (D-WI-2) Rep. Maurice Hinchey (D-NY-22) Rep. Gwen Moore (D-WI-4) Rep. San Hayworth, M.D. (R-NY-19) Rep. Ed Perlmutter (D-CO-7) Rep. David E. Price (D-NC-4) Rep. Mazie Hirono (D-HI-2) Rep. Ron Kind (D-WI-3) Rep. Dan Boren (D-OK-2) Rep. Bill Posey (R-FL-15)

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 bistory.*

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.

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.*
- Click on **NIH 2013 Budget Action** to send an email on this issue to your representatives.

Be an advocate for digestive health. Thank you!





Digestive Health Advocates Raising Awareness and Funds for Research

You Can Help!

There are various ways you can contribute to raising the standards of care for functional GI and motility disorders – and ultimately finding cures. You can take action in all kinds of ways, from making a donation to participating in an event to organizing an event or creating an online fundraiser.

All are fun ways to support the cause and raise money for research. If you're new to fundraising, we'll show you the ropes and help get you on your way to planning a successful event.

Here are several event and fundraising pages currently posted on DHA.org, the Digestive Health Alliance website. Goals range from \$100 to \$10,000. Proceeds from your tax-deductible donations go to IFFGD/DHA to support research.

Event and Online Fundraiser

Awareness Walk for Gastroparesis Bellingham, Washington

When: Saturday, September 8, 2012

Start Place: Bellingham Farmer's Market, Depot Market Square, 1100 Railroad Ave., Bellingham, WA

Start Time: Noon



Welcome to the **first annual Awareness Walk for Gastroparesis (GP) in Bellingham, WA**! The event will take place Saturday, September 8th, beginning at the farmer's market at noon. We will walk down the interurban trail along the bay towards Boulevard Park, wrap around Woods Coffee and back to the market. A booth will be set up for registration and important information about GP. T-shirts will be available and a selection of exciting raffle prizes to give away.

My Motivation – My name is Stephanie and I have gastroparesis, a debilitating, life-altering digestive disorder that affects more than 1.5 million Americans and many more worldwide. The stomach's ability to contract and properly digest food becomes a thing of the past and many are left with chronic side effects including nausea, vomiting, pain, malnourishment and fatigue. Little is still known about this disorder and to date there is no known cure. Patients are left to rely on restricted diets, medications, unwanted procedures and at times, feeding tubes to survive. Your support is appreciated so that we can help fund further research and treatment options to not only improve but to save the lives of so many people suffering front gastroparesis. Thank you and we look forward to your support and hope to see you at the Walk!



Goal: \$ 10,000.00 **Donate at:** www.dha.org/awareness-walk-for-gastroparesis

My Story - In 2008, I was diagnosed with gastroparesis, at the age of 28, after experiencing extreme digestive distress and losing over 20 pounds in less than 2 months. It drastically changed my life, disabling me not only from eating normally, but getting enough exercise, obtaining my master's degree, working, and living a fulfilled life like most young women do. Like many other patients, I have gone through a number of medications and procedures, including having a feeding tube placed in August of 2011, the only option left to save my life. Since then I have learned numerous ways to manage this illness through a dietary and lifestyle modifications, which in itself can seem like a full-time job at times. Currently, I work as a Health Coach (www.journeywithgp.com), inspiring and teaching others to make the best of what they have. It is my intention to promote advocacy and raise as much awareness as possible to help the millions worldwide living with this life-altering illness.

Event and Online Fundraiser

The fight for Hirschsprung's Disease

Daytona Beach, Florida

My Motivation – Every day is a struggle for my son, Tyler, who has Hirschsprung's disease as well as Autism. Seeing him battle everyday has inspired me to reach out to other parents and organizations to try and raise awareness for this cruel disease.



Goal: \$ 1,000.00 Donate at: www.dba.org/fight-for-birschsprungs

My Story – Tyler was brought into this world a miracle, he was born at 26 weeks. At birth he was diagnosed with respiratory problems, heart problems, liver problems as well as Hirschsprung's disease (HD), and just this year, Autism. Tyler started kindergarten this year and it has been a struggle; every day he was sent home for going to the bathroom on himself. He also has to deal with kids making fun of him every day because he has to wear diapers at 6 years old. Tyler also has to see about six different doctors a month. He has to be closely monitored by a nutritionist. Due to HD taking all the nutrients from him, he has failure to thrive and is currently 36 lbs. The doctors tell me he is never going to be "normal," which is why I want to raise awareness. One in 5,000 babies in the U.S is diagnosed with HD. This disease has no cure and if left untreated it can take a life. I am glad I did my research and came across IFFGD. All proceeds will go to raise awareness for HD and to find a cure. Thank you.

Online and In Person Fundraiser

Give a Quarter, Save a Quarter! A Piggy Bank Tale Catonsville, Maryland

I placed a piggy bank out at work and a sign that read: 25% of Americans have a functional GI disorder, most commonly irritable bowel syndrome (IBS). Often, it will be someone you already know! These types of disorders can be unmanageable at times and this is when your support is needed! By giving a quarter, you are funding research for the treatment of disorders like IBS, chronic constipation, GERD, dyspepsia, and many more. 100% of contributions go to The International Foundation For Functional GI Disorders.



Goal: \$ 100.00 **Donate at**: www.dba.org/give-a-quarter

My Story – This is important to me because I have suffered silently for a long time. When you have a functional GI disorder, everything is affected. Your family, your friends, your work life, school and studying... I was only 17 years old when I was diagnosed with IBS and Functional Abdominal Pain Syndrome. A senior in High School. What should have been the most fun years of my life in college were terrible. Every day I was in pain, both physically and psychologically. IFFGD helps with both. They try and find the best doctors, present research findings, and lend support. DHA is just another branch of this wonderful organization that needs our support!

Help Find Cures for Children

The DHA Children's GI Research Network carries out research projects and advances science in order to improve diagnosis and treatment of digestive disorders in children. You can help by supporting the Network with your donation. Go to our web page at *www.dha.org/content/kids-gi* to find out more, or contact IFFGD.

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

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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.



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