



International Foundation for  
Functional Gastrointestinal Disorders

**IFFGD**

*Information. Assistance. Support.*

# Digestive Health Matters

Participate in your own health care | Vol. 20, No. 3, © 2011 IFFGD

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*A Little Knowledge can Make a Big Difference*

*www.iffgd.org*

## Dear Readers,

In the twenty years since IFFGD was formed, the organization has brought about incredible change in the field of functional GI and motility disorders (FGIMDs). We have provided assistance and hope to patients, research funding and medical education to professionals, and awareness to the public and to policy makers on Capitol Hill.

All of these efforts, first and foremost, have been designed to help patients. We have sought to legitimize these disorders so that patients are no longer marginalized by their doctors and by society because of their disorder. We have sought to increase the number of healthcare providers who are available to understand and treat these disorders. We have sought to bring about improved treatments so that people can finally find relief from their suffering. While there is still a long way to go, through all these efforts we have helped change the way FGIMDs are viewed.

But we did not accomplish these changes alone. Our most critical ally has always been you. Every person who has shared their story, who has written to their congressperson, who has made a donation, who has been a member, has been a champion for this cause. Our achievements would have been impossible without you.

We have always recognized the power of the collective voice in bringing about change. In the last issue we announced the creation of the Digestive Health Alliance (DHA), IFFGD's new grassroots initiative.

We are now pleased to announce that the DHA website, [www.DHA.org](http://www.DHA.org), is now live and ready to help you recognize the power of your own voice.

DHA.org is, first and foremost, your website. The site is structured around Communities of people who share an interest in related GI disorders. In these Communities, you can easily find the people and topics most relevant to you. Membership on the website is free.

Once you are registered, you'll find that DHA.org is whatever you want it to be: a mechanism for bringing about policy change or a safe place to find support; a place to mobilize or to socialize; a place to lead or to follow. You can read articles and stories, create fundraising events or blogs, participate in discussions, or just show your support for the causes that matter most to you. Whatever you seek to accomplish, DHA.org will provide the tools to make it possible.

We invite you to visit the website and start being your own champion today.

Thank you.

Susan E. Schneck, M.A.

IFFGD Program Specialist



➔ **GET HELP**

➔ **TAKE ACTION**

➔ **GET STARTED**



# Support the DHA Children's GI Research Network

Many children suffer with painful, disabling, and in some cases life-threatening functional GI and motility disorders (FGIMDs). The majority of these conditions progress into adulthood and become increasingly costly and difficult to manage. The DHA Children's Research Network was established to connect pediatric GI research centers across the country so that data can be shared and collaborative research projects can be conducted. The Network is currently executing projects designed to improve diagnosis and treatment of FGIMDs in children.

## Past, Current, and Future Projects

*Pre-Network* – As recently as the early 2000's, many FGIMDs in children were not widely recognized as "legitimate" conditions.



While it is now accepted that these conditions have underlying biologic mechanisms, more needs to be done to better understand how these conditions develop and manifest themselves. The persistent lack of fundamental understanding surrounding these conditions has led to a situation where accurate recognition and diagnosis can be difficult, and physicians have few effective treatment options and no cures.

*Today* – Thanks to your support and generosity, DHA Children's GI Research Network has taken the lead in the efforts to identify and validate diagnostic criteria, and it is helping to develop innovative treatment options. The Network currently serves as a forum in which experts from different specialties can come together, discuss the different medical aspects of childhood FGIMDs, and outline an agenda for future research.

In addition, the Network serves as the infrastructure that allows investigators to collect and share information from various sites across the country by utilizing a web-based data registry and the Research Informatics Core at Nationwide Children's Hospital in Columbus, Ohio.

Initial projects are aimed at validating "red flags" (alarm signs) to improve diagnosis, and studying short and medium range



outcomes for children suspected of having FGIMDs to better identify potential treatments. These projects are intended to establish the foundation for critically important large, longitudinal research studies, which we hope to execute moving forward.

*Tomorrow* – The next steps in the process to improve diagnosis and treatment of childhood FGIMDs have been identified below by the medical

experts affiliated with the DHA Children's GI Research Network. With your generosity and support, we can initiate these research projects as soon as we have the funding for them.

## Your support can help make these future projects a reality.

➔ Bring an additional 5 centers into the Network to expand patient participation in research projects, and ultimately increase data collection and information sharing to improve the quality of data collected.

➔ Conduct a comprehensive evaluation of inter-individual (and inter-center) variability in the diagnosis and treatment of children with FGIMDs and how this variability impacts health outcomes.

➔ Establish a tissue / serum bank to study genetic factors involved in the development of FGIMDs and the mucosal factors involved in the biological and physical expressions (pathophysiology) of childhood FGIMDs.

## Network Researchers

### DHA Children's GI Research Network

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## Action Alert!

### Your Help is Needed

Urge your Member of the U.S. House of Representatives to cosponsor the ***Functional Gastrointestinal and Motility Disorders Research Enhancement Act of 2011 (H.R. 2239)***. Functional GI and motility disorders include conditions such as dysphagia, gastroesophageal reflux disease (GERD), dyspepsia, cyclic vomiting syndrome, gastroparesis, irritable bowel syndrome (IBS), Hirschsprung's disease, chronic intestinal pseudo-obstruction, bowel incontinence, and many others. They affect the esophagus, stomach, gallbladder, small and large intestine, and anorectal areas of the body.

Your help is needed to see that this bill is passed – *all you need to do is call or send an email to your House Member asking him or her to cosponsor H.R. 2239.*

### Background

In an effort to bolster federal research into functional gastrointestinal and motility disorders (FGIMDs) and improve the development of innovative treatment options for these conditions, IFFGD and grassroots advocates have been working with legislators to introduce the first ever federal research bill focused on FGIMDs. We are pleased to announce that as a result of this sustained congressional outreach, the ***Functional Gastrointestinal and Motility Disorders Research Enhancement Act of 2011*** has been introduced in the U.S. House of Representatives with bill number H.R. 2239.

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

### The Issue

H.R. 2239 was introduced on a bipartisan basis by Congressman F. James Sensenbrenner, Jr. (R-WI-5) and Congressman James Moran (D-VA-8h). This means that members of both political parties can support the bill, which initially has 2 supporters in Congress.

In order for H.R. 2239 to become law and for its research and treatment related provision to take effect, the bill needs more support in the U.S. House of Representatives. Your Representative can support H.R. 2239 by becoming a cosponsor. Once 218 Representatives cosponsor this bill, the U.S. House of Representatives will pass it.

However, your Representative will only become a cosponsor if YOU – their constituent – ask them to support H.R. 2239.

### Here's What You Can Do

- Most effectively, contact IFFGD and we will help you craft a message that you can email or fax back to us and we will hand deliver it to your House Representative.
- If you would like to join with others in a growing grassroots network conducting coordinated congressional outreach on this issue, please contact IFFGD, and express your interest in advocacy. Email Selena La Porte at [slaporte@iffgd.org](mailto:slaporte@iffgd.org) or phone 414-964-1799.

### GERD Awareness Week

The 13th Annual GERD Awareness Week is November 20-26, 2011. Every November, we expand our efforts to support GERD Awareness Week through public service and media outreach.

During this time (and at any time), we encourage people experiencing symptoms, which may be GERD-related, to check our website at [www.aboutGERD.org](http://www.aboutGERD.org) or call the IFFGD Helpline toll-free at 888-964-2001 to receive information and support regarding GERD.

IFFGD first designated GERD Awareness Week in November 1999, and every subsequent year we work to focus attention on important health messages about GERD diagnosis and treatment. GERD Awareness Week is listed on the U.S. National Health Observances calendar. The U.S. National Health Information Center (NHIC) Office of Disease Prevention and Health Promotion describes health observances as days, weeks, or months devoted to promoting particular health concerns. Health professionals, teachers, community groups, and others can use these special times to sponsor health promotion events and stimulate awareness of health issues.



# Things to Know about Gastroesophageal Reflux Disease

Heartburn is so common that its potential significance may be overlooked. But frequent heartburn may be the sign of GERD. It is important to recognize that GERD is a disease. It is not caused by lifestyle or dietary decisions. If ignored or not appropriately treated, GERD can lead to more serious complications. If you suspect you may have GERD, the first step is to see a doctor to obtain an accurate diagnosis. Then work in partnership with your doctor to initiate the best available treatment plan for you.

## Signs and symptoms

GERD is characterized by symptoms and/or tissue damage that results from repeated or prolonged exposure of the lining of the esophagus to contents from the stomach. Heartburn is the most common symptom of GERD, so talk to your doctor if:

- Your heartburn happens 2 or more times a week
- Your heartburn gets worse
- Your heartburn happens at night and wakes you from sleep
- You've had heartburn now and then, but for several years
- You have difficulty or pain when swallowing
- Your discomfort or pain interferes with your daily activities

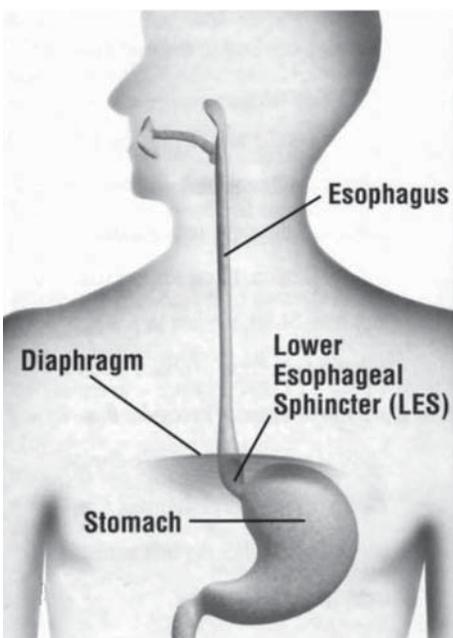
Chronic heartburn is the most common – but not always the only – symptom of GERD. Acid regurgitation (refluxed material into the mouth) is another common symptom. Other less common symptoms may be associated with GERD.

These may include:

- Belching
- Difficulty or pain when swallowing
- Waterbrash (sudden excess of saliva)
- Dysphagia (the sensation of food sticking in the esophagus)
- Chronic sore throat
- Laryngitis
- Inflammation of the gums
- Erosion of the enamel of the teeth

- Chronic irritation in the throat
- Hoarseness in the morning
- A sour taste
- Bad breath

Chest pain may indicate acid reflux. But this kind of pain or discomfort should prompt urgent medical evaluation to identify the cause including possible heart conditions.



## Causes of GERD

There is no known single cause of GERD. Reflux occurs when the lower esophageal sphincter (LES) barrier does not work as it should or is somehow overwhelmed.

## Treatments for GERD

GERD is a recurrent and chronic disease for which long-term medical therapy is usually effective. It is important to recognize that chronic reflux does not resolve itself. There is not yet a cure for GERD. Long-term and appropriate treatment is necessary. The goals of treatment are to control or reduce symptoms, heal an injured esophagus, and manage or prevent complications.

Treatment options include:

- Lifestyle modifications
- Medications
- Surgery
- Combination of methods

Endoscopic treatments for GERD are newer and are still being studied, so less is known about how well they work or how safe they are.

## Lifestyle Modifications

Lifestyle modifications mean changing things we have control over. It means avoiding factors that may bring on symptoms or make them worse, such as dietary changes or changes in daily routine. While diet does not cause GERD, reflux and its most frequent complaint of heartburn can be brought on by foods. Certain medications can worsen symptoms. Let your doctor know about any medicines you take.

## Medications

The most commonly prescribed medicines to treat GERD are H2RAs (histamine type 2 receptor antagonists – also known as H2 blockers), and PPIs (proton pump inhibitors).

H2 blockers reduce the amount of acid produced in your stomach, which lowers your chance of getting heartburn. All H2 blockers are available both by prescription and over-the-counter. Proton pump inhibitors (PPIs) are more powerful medicines that limit acid secretion in your stomach. Most PPIs are only available by prescription, but some are available over-the-counter.

Over-the-counter preparations provide only temporary symptom relief. They do not prevent recurrence of symptoms or allow an injured esophagus to heal. They should not be taken regularly as a substitute for prescription medicines – they may be hiding a more serious condition. If needed regularly, for more than two weeks, consult a physician for a diagnosis and appropriate treatment.



## Surgery

For some people, surgery to strengthen the barrier between the stomach and esophagus may be a treatment option for acid reflux. This surgery to treat GERD is called a “fundoplication.” In a fundoplication, the top part of the stomach is wrapped around the bottom of the esophagus and attached there. This helps strengthen the muscle at the bottom of the esophagus that closes to keep food and acid from coming back up.

When performed by an experienced surgeon, fundoplication surgery may work as well as a well planned and carefully taken medical treatment with a proton pump inhibitor. However, medicine may still need to be taken after surgery to control symptoms.

## Talking to Your Doctor

A diagnosis of GERD should be made by a doctor. Be sure to talk to your doctor about any treatment plan for GERD. If your doctor prescribes a medicine, understand the dosage and take it as directed. You may need to take a medicine long-term to control your GERD. At later visits, ask your doctor if your effective dosage can be reduced. If your doctor recommends surgery, review all aspects of the procedure with your gastroenterologist and the surgeon.

Ask about risks as well as benefits. Remember, side effects can occur with any treatment. Understand the possible side effects and learn what you can do to minimize or avoid them.

## Learn More

IFFGD has information available to help you learn more about GERD and managing the condition. Call us toll-free at 888-964-2001 or go to our website at [www.aboutGERD.org](http://www.aboutGERD.org).



## Susan's Ride for GERD

On Sunday, October 2, DHA Advocate Susan Schneck biked in the Pumpkin Pie Ride in Ottawa, IL to raise money for digestive health research. To learn more about her ride and to help support the cause, please visit her page on the Digestive Health Alliance website at [www.DHA.org/fundraising/susan](http://www.DHA.org/fundraising/susan)



## Research News

Here are summaries of some recent research and treatment news.

### New Guides Compare Benefits and Risks of GERD Treatments

New plain-language publications from the U.S. Department of Health and Human Services' (HHS) Agency for Healthcare Research and Quality (AHRQ) compare the benefits and risks of treatments for gastroesophageal reflux disease (GERD). The digestive condition affects millions of Americans and can be treated with medications or surgery. The publications are based on an updated evidence report released on September 23, 2011.

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

The AHRQ report found that Proton Pump Inhibitors (PPIs) tend to be more effective than other drugs, but comparisons show few consistent differences between PPI types or dosages. PPIs cause some side effects, such as diarrhea and headaches, but these were generally not serious.

GERD, sometimes known as acid reflux disease, occurs when stomach contents frequently back up into the esophagus. GERD often causes heartburn, which occurs when stomach acid irritates the esophagus. Some patients with GERD develop a condition called Barrett's esophagus, a disorder in which the lining of the esophagus is damaged by stomach acid, which can increase the risk of esophageal cancer.

Many patients have frequent, severe symptoms requiring long-term regular use of antireflux medications. For these people with chronic GERD, the goals of therapy usually are improvement in symptoms and quality of life and the prevention of complications such as Barrett's esophagus. However, experts remain unsure how best to achieve this.

The report also found that fundoplication, surgery in which the upper portion of the stomach is wrapped and sewn around the esophagus, decreased, but did not eliminate, the use of antireflux medications. In addition, some patients who underwent antireflux surgery demonstrated improvement in reflux symptoms and quality of life. However, the report found severe side effects associated with surgery, including postoperative infections, difficulty swallowing, and postmeal bloating.

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

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

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



### Barrett's Esophagus

In a small number of patients with GERD, a complication has been identified as a potentially pre-cancerous condition. The condition is called Barrett's esophagus. The number of people who develop Barrett's esophagus is relatively small. If Barrett's esophagus is present, talk to your doctor about regular endoscopic screening. In the absence of Barrett's esophagus, there is no strong evidence that GERD is a risk factor for developing cancer.

## New VA Rule Helps Veterans with Functional GI Disorders

On Monday, August 15, 2011 the Department of Veterans Affairs (VA) implemented a new rule with broad, positive implications for the functional gastrointestinal and motility disorders (FGIMDs) community. This rule states that there is a “presumptive service connection” for veterans affected by functional gastrointestinal (GI) disorders who served in Southwest Asia during the Persian Gulf War.

This federal policy decision means that if a veteran deployed during the Persian Gulf War now suffers with a functional GI disorder, it is presumed that they developed the condition as a result of their military service for the purposes of assessing disability benefits. You can read the rule in the Federal Register on our web page at [www.iffgd.org/pdfs/VA-FR-Notice-FGIDs.pdf](http://www.iffgd.org/pdfs/VA-FR-Notice-FGIDs.pdf).

Functional GI disorders disproportionately impact veterans and active duty military personnel. Deployed soldiers face a heightened chance of developing a functional GI disorder due to their exposure to certain risk factors, such as infections of the GI tract and severe stress. This link is well documented in medical literature, including 2 pivotal National Academy of Sciences reports on health effects of serving in the Gulf War, which were critical in supporting the VA's final rule.

For many years, IFFGD has been working with lawmakers and government officials to see that meaningful steps are taken to improve care and bolster research for our FGIMDs-affected veterans and active duty military personnel. VA's recent action is a key indicator of how community advocacy and grassroots efforts to raise awareness of FGIMDs have been successful in legitimizing the seriousness of these conditions.

We remain concerned, however, that while veterans with functional GI disorders now

have improved access to care and benefits, effective treatment options remain limited. This leads to a situation where veterans may be disabled by a functional GI disorder, but lack treatment options that could return them to a productive lifestyle. This treatment gap needs to be addressed (as it does for everyone with a functional GI or motility disorder), and one important way to address it is through new research led by the Department of Defense (DOD).

## U.S. Senate Action Needed

On Wednesday, June 22, 2011 IFFGD was 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) 2012 Defense Appropriations Bill, and Senators are considering adding “functional GI disorders” to the list of conditions eligible for study through the DOD Peer-Reviewed Medical Research Program. The DOD research program is intended to only fund research into conditions that disproportionately impact military personnel or are related to military service. View IFFGD's testimony on our web page at [www.iffgd.org/site/advocacy/legislative-alerts/action#va-dod](http://www.iffgd.org/site/advocacy/legislative-alerts/action#va-dod).

IFFGD being asked to testify sends a strong signal that the Senate is seriously considering adding “functional GI disorders” to the DOD Peer-Reviewed Program's list of conditions eligible for study in FY 2012. However, the Senate will only follow-through on this request if individual Senators hear from their constituents (you) that they should take action on this issue. Now that VA has issued this presumptive service connection for functional GI disorders our justification for being part of DOD medical research activities has never been stronger.

## You can Help

Reach out to your U.S. Senators through IFFGD in a coordinated effort to request that they “include functional GI disorders on the DOD Peer-Reviewed Medical Research Program's eligible conditions list within FY 2012 defense appropriations legislation.” Please contact IFFGD by Email at [dha@iffgd.org](mailto:dha@iffgd.org) and indicate your willingness to do so. Thank you.



*Testifying before Senate Defense Appropriations Subcommittee*

*[Note: In September 2011, the U.S. Senate Appropriations Committee in their fiscal year 2012 budget recommendation urged the NIH National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) to collaborate with the Department of Defense and the Department of Veterans Affairs to advance research of functional gastrointestinal disorders in patients with gulf war syndrome. See the Legislative Update on page 20.]*

## Better Understanding and More Education about Gastroparesis Needed

A research group from University of Louisville School of Medicine in Kentucky conducted a survey of physicians to determine physicians' perception of gastroparesis and identify areas that need further research and education. The survey included questions on the causes, symptoms, management, and perceived complications of gastroparesis. A total of 397 physicians participated in the national survey.

Gastroparesis is a disorder in which the stomach empties very slowly. Symptoms can vary from person to person and range from mild to severe. Clinical characteristics that indicate the severity of gastroparesis are poorly defined. Objective markers for complications of severe gastroparesis are lacking. Misconceptions of gastroparesis among physicians may be common. Because of symptom overlap with functional dyspepsia, gastroparesis may be under-recognized and misdiagnosed.

The researchers found that more physician awareness and education are needed on gastroparesis and the standardized four-hour gastric scintigraphy diagnostic method. They also concluded that more research is needed on abdominal pain in patients with gastroparesis and to clarify the management strategy for this condition.

*Source: Drossman DA, Chang L, et al. Severity in irritable bowel syndrome: a Rome Foundation working team report. Am J Gastroenterol. 2011 Jul 12. doi: 10.1038/ajg.2011.201. [Epub ahead of print]*

## Defining Severity in Functional GI Disorders

Any treatment plan for a functional GI disorder, as well as for most other diseases, is determined in part by the severity of the condition in an individual. But agreement on what defines severity of functional GI disorders has been lacking. To address this, the Rome Foundation, through a Working Team consensus report, has developed guidelines to better describe severity looking at IBS, the most studied functional GI disorder.

Unlike many diseases where severity can be measured by abnormality in blood or tissue markers, severity in functional GI disorders is determined by symptom reports and patient experiences. Understanding and standardization of severity in functional GI disorders will help with clinical research, therapeutic development, and effective treatment.

The Rome Foundation findings are as follows:

- Severity is defined by a composite of reported...
  - » Symptoms in the GI tract
  - » Symptoms outside the GI tract
  - » Degree of disability
  - » Degree that illness relates to activities

- Severity is affected by biological function and activity factors in both the GI tract and the central nervous system
  - » As severity increases, the central nervous system provides a greater contribution
- Severity is related to and influences health-related quality of life and behaviors, and also guides diagnostic and therapeutic clinical decision making
- Severity can be subcategorized into clinically meaningful subgroups as mild (about 40 %), moderate (about 35 %), and severe (about 25 %), and this provides a working model for use in future research and clinical care

These new findings incorporated 3 recently published studies that were aimed at gaining additional knowledge about factors influencing severity: a qualitative focus group of 16 IBS patients conducted in collaboration by the Rome Foundation and the International Foundation for Functional Gastrointestinal Disorders (IFFGD); a survey of 755 tertiary-care IBS patients from the UCLA database; and an Internet survey of 1,966 IBS patients conducted in collaboration by IFFGD and the University of North Carolina in Chapel Hill.

Future work is required to understand more precisely the factors contributing to severity and to develop a valid patient-reported instrument to measure severity in the functional GI disorders.

*Source: Drossman DA, Chang L, et al. Severity in irritable bowel syndrome: a Rome Foundation working team report. Am J Gastroenterol. 2011 Jul 12. doi: 10.1038/ajg.2011.201. [Epub ahead of print]*





# Managing Incontinence: A Survey of Those Who Live With It

By: International Foundation for Functional Gastrointestinal Disorders (IFFGD), Milwaukee, WI

Many otherwise healthy, active people suffer from incontinence or loss of bowel control. Fecal incontinence (FI) is also called bowel incontinence. It strikes men and women of all ages and involves the accidental loss of solid or liquid stool. Incontinence is a long-term, stressful, and limiting disorder.

An effective treatment and management plan for incontinence minimizes episodes and allows individuals to regain a sense of personal control. Treatments are tailored to address each person's specific symptoms and may include a number of approaches.

In 2010, IFFGD conducted an online survey to help explain what it is like to live with and manage incontinence from the point of view of those who experience the condition. A total of 142 individuals completed an Internet-based survey between September and December, 2010. All indicated that they experience FI not caused by irritable bowel syndrome (IBS) or other intestinal diseases. Ninety-seven (68%) of the survey responders indicated they had never been diagnosed by a physician; forty-five (32%) responders indicated they did have a physician diagnosis. Responders were recruited primarily from the International Foundation for Functional Gastrointestinal Disorders (IFFGD) websites.

## KEY FINDINGS

### Reported Characteristics of Bowel Control/FI Problems:

- About two-thirds of the responders suffer from the symptoms of FI but have not been diagnosed; one-third have been diagnosed.
- Almost half of diagnosed patients and more than one-fourth of those not diagnosed experience a loss of bowel control 4 or more times per week.
- More than half of all responders experience loss of bowel control primarily during the day, and for most, the stool is usually loose/watery.
- Close to two-fifths of diagnosed FI patients and almost half of undiagnosed individuals say the severity or frequency of their FI changes throughout the year.
- FI patients who are diagnosed typically report that the condition "often" or "always" interferes with their daily activities; those who have not been diagnosed are more likely to say it "rarely" interferes.
- The majority of responders say they missed social activities in the past 3 months due to their FI.

### Interaction with Physicians

Most of the people who had a diagnosis of FI talked to their physicians within 3 years after their symptoms first began. Typically, these individuals consulted 1 or 2 physicians before receiving a diagnosis; and more than one-third visited 3 or more physicians before receiving their diagnosis. Most talked first about it with a primary care physician or OB/GYN, although the largest proportions are currently treated by a gastroenterologist. One out of five said their doctors have not specified a cause. Those who know a cause most frequently mention either an obstetrical injury or a rectal injury.

The majority of responders in this survey had not been diagnosed with FI. They gave a variety of reasons for this, most often saying:

- They are too embarrassed to bring it up.
- They feel they can manage the condition on their own.
- They have mentioned it, but their physicians implied there is not much to be done about it or it is a normal part of aging.

### Treatment

Responders diagnosed with FI were asked about how their FI was being treated by their physician, choosing from a list that included: changes in diet; over-the-counter anti-diarrheal medicine; fiber; stool softeners; over-the-counter laxatives; prescription laxatives; enemas; biofeedback or Kegel training; surgery; or colostomy.

- Patients diagnosed with FI and who use the treatments listed in the survey have spent, on average, \$250 per year on these treatments.
- The majority of patients are using diet and/or medications to relieve their FI.
  - » Most patients like this treatment approach because it is something they can do themselves.
  - » More than one-third of patients using this approach feel that the treatment does not really improve their conditions.
- Three-fourths of FI patients agree with the statement, "Even if I follow my treatment exactly, there seems to be times when it is not working." More than two-thirds agree that, "No treatment for FI works completely." Two-thirds agree that, "It is comforting to know that there are other people who suffer from FI."



## DETAILED FINDINGS

### Making the Diagnosis

A diagnosis is the first step in putting together a treatment plan for incontinence. Patients need to speak with doctors candidly about bowel symptoms and doctors need to ask frankly about loss or leakage of stool. Once incontinence is identified in a person, the cause, severity, and treatment plan can be established.

- Over two-thirds (68%) of the responders suffer from the symptoms of fecal incontinence but have not been diagnosed.
- Patients diagnosed with FI typically have had the condition for more than 3 years, while those who have not been diagnosed tend to report time periods of less than 3 years.
- The largest portion of patients who have been diagnosed with FI were diagnosed more than 10 years ago (38%). The largest portion of patients not diagnosed report a time period of 1–4 years (36%).
- Patients under the age of 55 are more likely than are older patients to say they have had FI for more than 10 years (30% vs. 11%), while older patients are more likely than younger patients to have had FI for 1 to 3 years (45% vs. 25%).

| Length of Time with FI | Diagnosed | Not diagnosed |
|------------------------|-----------|---------------|
| More than 10 years     | 38%       | 13%           |
| 4 to 10 years          | 27%       | 26%           |
| 1 to 3 years           | 29%       | 36%           |
| Less than 1 year       | 7%        | 25%           |

### Talking about it

- The large majority of patients (80%) who have been diagnosed with FI talked to their physicians about it within the first 3 years, including 40% who mentioned it within the first year.
- One-fifth (20%) waited 4 years or more, including 7% who waited more than 10 years before mentioning it.

| Time with FI before Seeking Medical Advice | Diagnosed |
|--|-----------|
| More than 10 years                         | 7%        |
| 4 to 10 years                              | 13%       |
| 1 to 3 years                               | 40%       |
| Less than 1 year                           | 40%       |

### Symptom Patterns and Severity

Incontinence can affect nearly every aspect of daily life. People with incontinence live with the uncertainty of never being sure when an episode might strike.

- Patients in both diagnosis groups experience their FI frequently:

| Frequency                  | Diagnosed | Not diagnosed |
|----------------------------|-----------|---------------|
| At least 1 time per week   | 83%       | 70%           |
| At least 2 times per week  | 76%       | 60%           |
| At least 4 times per week  | 47%       | 27%           |
| At least 10 times per week | 16%       | 8%            |

- The majority of responders (71% diagnosed, 57% not diagnosed) experience loss of bowel control primarily during the day.
- More than half (58% diagnosed, 65% not diagnosed) say their stool is usually loose or watery, and more than one-quarter say that stool consistency varies (31% diagnosed, 27% not diagnosed).

| Stool Consistency with FI | Diagnosed | Not diagnosed |
|---------------------------|-----------|---------------|
| Varies                    | 31%       | 27%           |
| Loose or Watery           | 58%       | 65%           |
| Hard or Firm              | 11%       | 8%            |

- Two-fifths (38%) of responders who have been diagnosed with FI and almost half (48%) who have not been diagnosed say that the severity or frequency of their FI changes throughout the year.

### Daily Living and Quality of Life

People who experience incontinence endure an emotional burden of embarrassment as well as physical burden of discomfort and disruption of daily living – including work and social activities.

- Patients who are diagnosed with FI most often report that the condition “often” interferes with their daily activities (40%), and the remainder report that it “always” (29%) or “sometimes” (31%) interferes.
- Those who have not been diagnosed most often say that their FI “sometimes” interferes (38%). However, one-fifth (19%) say it “rarely” interferes.



## Frequency that FI Interference with Daily Activities

| Frequency | Diagnosed | Not diagnosed |
|-----------|-----------|---------------|
| Always    | 29%       | 20%           |
| Often     | 40%       | 24%           |
| Sometimes | 31%       | 38%           |
| Rarely    | 0%        | 19%           |

## Missed Work or Social Activities During Previous 3 Months due to FI

| Frequency                | Diagnosed | Not diagnosed |
|--------------------------|-----------|---------------|
| Missed work              | 38%       | 26%           |
| Missed social activities | 73%       | 55%           |

- More than one-third (38%) of patients who have been diagnosed with FI and one-quarter (26%) of those who have not been diagnosed say they have missed work in the previous 3 months due to their FI.
- Of those who missed work, more than half (53% diagnosed, 52% not diagnosed) missed 4 or more days due to their FI.
- The majority of all responders say they had missed social activities in the previous 3 months due to their FI (73% of diagnosed and 55% of undiagnosed). Over one-third of those who missed activities because of their FI missed more than 5 activities.

## Interactions with Physicians

Plain spoken and direct communication between doctors and patients about symptoms is important to making a diagnosis and finding the right treatment. Individuals with FI may be hindered by social stigma, discomfort talking about symptoms, or lack of awareness that potential treatments are available.

- Two-thirds (68%) of the survey responders do not have a diagnosis of FI from a physician. When asked why they have never been diagnosed by a physician, they most often report that:
  - » They have mentioned it to their doctors, but the doctor implied either that there is not much that can be done about FI or that it is a normal part of aging (23%).
  - » They are too embarrassed to bring it up to their doctors (20%).
  - » They believe they can manage it on their own (15%).
- Of the one-third (32%) of responders who do have a physician diagnosis of FI, 38% say they first discussed their condition with their primary care/family physician, followed by 22% who spoke to a gastroenterologist, 13% to an OB/GYN, and 11% to a colorectal surgeon.

- More than one-third (36%) of patients with FI are currently being treated by a gastroenterologist, 24% see a colorectal surgeon for treatment, 22% are treated by a primary care/family physician, and 7% by an OB/GYN.
- Most patients consulted more than one physician before they were diagnosed as having FI.

| Number consulted       | 1 doctor | 2 doctors | 3–4 doctors | 5 or more doctors | Do Not Recall |
|------------------------|----------|-----------|-------------|-------------------|---------------|
| Percentage of Patients | 22%      | 33%       | 37%         | 4%                | 4%            |

- Most patients diagnosed with FI (20%) report that their doctors attributed their bowel control problems to an obstetrical injury, followed by 16% who mention an anorectal injury, and 9% who mention a spinal cord injury.
- Almost one-fifth of patients (18%) indicate that their doctors did not mention a reason for their bowel control problems.
- Only 44% strongly agree that their doctor is sympathetic and listens to them.



## Treatments

An effective treatment or management plan for incontinence not only makes episodes less likely, but also allows a person to regain a sense of personal control. Treatments are tailored to each person's specific symptoms. A treatment plan may include more than one method.

## Diet and Medicines

- Of those patients who have a diagnosis of FI, the majority (69%) are incorporating diet changes and/or medicine in their treatment plan.
  - » Patients report that they like this approach primarily because it is something they can do themselves (71%). Others state that they like it primarily because it is inexpensive (13%) or easy to do (6%).
- When asked what they like least about using diet and/or medicines to relieve their FI:
  - » 48% say it sometimes does not work, no matter how careful they are.
  - » 19% say it is hard to follow.
  - » 16% say they miss certain foods.
  - » 10% say they don't like the side effects from medications.

| Treatment                         | % of Patients Diagnosed * |
|-----------------------------------|---------------------------|
| Diet/Medicines (Net)              | 69%                       |
| OTC anti-diarrheal                | 42%                       |
| Fiber                             | 33%                       |
| Changes in diet                   | 31%                       |
| Stool softeners                   | 9%                        |
| Enemas                            | 9%                        |
| Surgery, such as sphincteroplasty | 13%                       |
| Biofeedback or Kegel training     | 11%                       |
| Colostomy                         | 2%                        |
| None of these                     | 22%                       |

\*Individuals may receive more than one treatment

- Forty percent indicate that they look at a lot of websites for help in understanding and treating their FI, and almost two-thirds (62%) indicate that they strongly agree with the statement that “It is comforting to know that there are other people who suffer from FI.”

### Satisfaction with Treatment

- More than half (56%) strongly agree that “No treatment for FI works completely,” and another 13% agree.
- More than two-thirds (69%) of responders strongly disagree with the statement, “I almost never have any ‘accidents’ since I’ve started/undergone treatment.”
- One-half (49%) disagree with the statement, “I have good control of my FI.”

### Summary

It is apparent from this survey that FI dramatically affects the quality of life of sufferers. For many individuals, the condition limits their social activities and affects their work life.

Embarrassment and lack of adequate communication between patients and doctors are barriers to obtaining a diagnosis. The degree that FI impacts on daily life may be the key factor in determining whether a patient seeks and obtains a diagnosis. Those with a diagnosis report more frequent episodes and more life impact than those who did not obtain a diagnosis.

Patients diagnosed with FI appear to be disappointed with currently available treatments, and over half are unhappy with how their condition and their feelings are sometimes treated by physicians. It is also clear from this survey that there is a considerable number of FI sufferers who do not realize that treatments are available and thus do not seek treatment for it from a physician.

Moreover, subsequent to this survey two new treatments for patients with FI who have failed more conservative therapies were FDA approved and are now available – InterStim sacral nerve stimulator, and Solesta injectable gel.

### Conclusion

Education and awareness can break down barriers to finding care and treatment. The public and healthcare providers need to be more aware of the symptoms, burdens, and treatments of FI. To help address this lack of awareness, in 2011 the National Institutes of Health (NIH) began a new program to help patients and health care professionals feel more comfortable talking about bowel control problems and addressing the needs of patients. The Bowel Control Awareness Campaign has Web resources available at [www.bowelcontrol.nih.gov](http://www.bowelcontrol.nih.gov).

Bowel control problems affect an estimated 18 million U.S. adults and the condition is believed to be widely under-diagnosed, according to the NIH. Incontinence is common across all ages; it does not have to be a part of aging. Importantly, there are a number of treatments and strategies to help improve continence. The first step, if you have incontinence, is to talk to your doctor.

IFFGD has many helpful resources. Visit our website at [www.aboutincontinence.org](http://www.aboutincontinence.org).

| Demographic Profiles of Survey Responders | Diagnosed | Not diagnosed |
|---|-----------|---------------|
| Under age 65 years                        | 80%       | 73%           |
| 18-34                                     | 11%       | 18%           |
| 35-44                                     | 13%       | 12%           |
| 45-54                                     | 36%       | 22%           |
| 55-64                                     | 20%       | 21%           |
| Female/Male gender                        | 80/20%    | 74/26%        |
| Employed                                  | 53%       | 50%           |
| Not able to work because of FI            | 9%        | 2%            |
| Uninsured                                 | 4%        | 10%           |
| Married or living as married              | 71%       | 60%           |
| College degree                            | 54%       | 43%           |

*We are grateful to Oceana Therapeutics for a grant in support of this survey.*

## Clinical Study

A clinical study or clinical trial (they mean the same thing) is a research study to answer specific questions about new products, therapies, or new ways of using known treatments. Clinical studies/trials are important in finding more and better treatments. Participation in clinical studies or trials offers one way to help advance GI research.

Here is a study at Mayo Clinic, Rochester that is seeking participants. You can find a list of more studies on our web page at [www.giresearch.org/site/gi-research/studies/nib](http://www.giresearch.org/site/gi-research/studies/nib).

### Take Part in Drug Therapy Study for Women with Urgency and Incontinence – Mayo Clinic Rochester, MN

This study is being done to learn if clonidine improves symptoms in women with rectal urgency and fecal incontinence (involuntary stool leakage). Clonidine is an approved drug for treating high blood pressure. Clonidine may reduce the symptoms of urgency and stool leakage, and give patients with fecal incontinence more time to reach the toilet.

The U.S. National Institutes of Health (NIH) is funding the study and will pay your study doctor or the institution to cover costs related to running the study.

### Payments

If you finish the study, you will receive \$ 600. This money is for the time you spend in this study. If you start the study but stop before finishing the study, you will receive part of this money.

### Who is eligible to participate in the study?

Women (aged 18-75 years) who experience fecal incontinence and urgency and do not have an organic disorder (e.g., rectal cancer, scleroderma, inflammatory bowel disease, significant rectal prolapse or neurological conditions).

### What is involved with this study?

The study lasts 8 weeks (4 weeks without study medication, then 4 weeks on medication/placebo). Bowel diaries and questionnaires are maintained during this period. Anorectal motility will be assessed before and after medication periods. A pelvic MRI will also be performed.

### Contact:

For more information or to participate in this research study, please call the research study coordinator . . .

**Jessica Edge at (507) 255-6802**

**Email: [edge.jessica@mayo.edu](mailto:edge.jessica@mayo.edu)**

Mayo Clinic, Rochester, MN



## 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. These books are published by outside publishers – not by IFFGD.

New to List

**Title:** Nausea: Mechanisms and Management

**Authors:** Robert M. Stern, Ph.D.; Kenneth L. Koch, M.D.; Paul L.R. Andrews, Ph.D.

**Publisher:** Oxford University Press (2011)

**Pages:** 462 (hardcover)

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

**Title:** Eating for Gastroparesis – Guidelines Tips & Recipes

**Author:** Crystal Zaborowski Saltrelli, C.H.C.

**Publisher:** CreateSpace (2011)

**Pages:** 90 (paperback)

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

**Title:** IBS – Free at Last

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

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

**Pages:** 126 (paperback)

This book describes an easy, step-by-step method for controlling IBS symptoms that may be caused by intolerance to certain carbohydrates (FODMAPS) in your diet. This approach is based on research, which has produced strong evidence that a group of short-chain carbohydrates, named FODMAPs are problematic for those with IBS; they are poorly absorbed in the small intestine and rapidly fermented by bacteria in the gut. The book includes information to help you understand the link between dietary sugars, starches, and fibers and IBS symptoms. It includes menus, tips on shopping and reading labels, and strategies for including your favorite foods in your diet. Available online at Amazon.com.

**Title:** Functional Pain Syndromes: Presentation and Pathophysiology

**Editors:** Emeran A. Mayer, M.D. and M. Catherine Bushnell, Ph.D.

**Publisher:** IASP Press (2009)

**Pages:** 580 (paperback)

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

**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](http://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 (hardback)

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 (hardback).

Five years in the making, Rome III is designed for "one stop" learning for health professionals. Available online at: [www.theromefoundation.org](http://www.theromefoundation.org).

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

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

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

**IFFGD INDUSTRY COUNCIL**  
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## Treatment News

### **Linacotide Approval Pending in the U.S. for Treatment of Irritable Bowel Syndrome with Constipation and Chronic Constipation, and in Europe for Treatment of Irritable Bowel Syndrome with Constipation**

Linacotide 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. Linacotide works by increasing the amount of fluid that flows into the bowel, allowing stool to pass more easily, and reducing visceral pain.

In August 2011 Ironwood Pharmaceuticals, Inc. and Forest Laboratories, Inc. submitted a New Drug Application (NDA) to the FDA for linacotide, a guanylate cyclase type-C (GC-C) agonist, for the treatment of IBS-C and of chronic constipation.

The submission 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 linacotide 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 linacotide-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 linacotide-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 linacotide 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 linacotide for the treatment of irritable bowel syndrome with constipation. Once approved, linacotide will be marketed in Europe under the trademark Constella®.

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



### Rifaximin Shows Promise for Treatment on Non-Constipated IBS

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

On February 24, 2011, Salix Pharmaceuticals announced that they expect the U.S. Food and Drug Administration (FDA) to seek additional information about rifaximin before considering it for approval for the treatment of non-constipation irritable bowel syndrome (Non-C IBS) and IBS-related bloating. The FDA may require that another clinical trial be performed, which could take years to complete.

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 statistically significant weekly findings in the primary endpoint and key secondary endpoint noted above were supported by daily findings in the secondary endpoints of global IBS symptoms, bloating, stool consistency and abdominal pain and discomfort. Additionally, the NEJM publication includes results of an analysis of a composite endpoint of abdominal pain or discomfort and loose or watery stools as outlined in the March 2010 draft FDA Guidance for Industry relating to the clinical evaluation of products for treatment of IBS.

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

Rifaximin is a gut-selective antibiotic with negligible systemic absorption and broad-spectrum activity in vitro against both gram-positive and gram-negative pathogens. It is currently approved by the 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.

### FDA Gives Marketing Approval for Metozolv™ ODT (Orally Disintegrating Tablets)

The FDA has granted marketing approval for the drug metoclopramide (Metozolv ODT) 5mg and 10 mg orally disintegrating tablets. The drug, marketed by Salix Pharmaceuticals, is indicated for the relief of symptoms associated with acute and recurrent diabetic gastroparesis in

adults and the treatment of symptomatic documented GERD in adults who do not respond to conventional therapy. Therapy should not exceed 12 weeks in duration. Metozolv ODT dissolves in the mouth. This could be helpful for patients who need a pro-motility and anti-emetic drug, but are unable to swallow pills or are unable to maintain oral intake due to nausea and vomiting.

In clinical studies, the most frequently reported adverse events (equal or greater than 2% occurrence) were headache, nausea, fatigue, somnolence/drowsiness, and vomiting.

*Important Safety Information –* Treatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible. The risk of developing tardive dyskinesia increases with the duration of treatment and the total cumulative dose. Treatment with metoclopramide 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.



## Legislative Update

IFFGD has been a voice on Capitol Hill for years on behalf of the digestive health community. Here is a summary of our latest activities.

### Priorities for 2011–2012

Each year we work to advance legislative priorities which are focused on bolstering research into functional GI and motility disorders and improving care for patients. We are making progress. Our 2011–2012 Legislative Agenda builds on our recent public policy successes and consists of the following 4 issues that *you can help make happen*:

- **Increased funding for the National Institutes of Health (NIH).** The NIH supports nearly all federal research into functional GI and motility disorders. Cutting the federal budget is fast becoming the focus of Congress and in this environment NIH could have its budget drastically reduced. Funding cuts for NIH could cripple research activities and delay important medical breakthroughs. Members of Congress must support increased funding for NIH and look at other areas of the federal budget for funding cuts.

» **Update** – On September 29, 2011 the House Appropriations Committee released a draft fiscal year (FY) 2012 Labor-HHS-Education funding bill. The draft provides NIH with \$31.7 billion in program funding, an increase of 3.3% compared to FY 2011. The Senate Appropriations Committee report for FY 2012 provides NIH with \$30.5 billion, a decrease of 0.6% compared to FY 2011. The full House and Senate will now consider funding proposals. *Ask your Senators to increase program funding for NIH.*



IFFGD Advocates on Capitol Hill

- **Increased Introduction and Passage of the *Functional Gastrointestinal and Motility Disorders Research Enhancement Act*.** The success of last year's IFFGD drafted Congressional Awareness Resolution on IBS and functional GI disorders (H.Res.1309) ignited an interest on Capitol Hill to advance a bill to bolster research and awareness into all the functional GI and motility disorders. As a result, we have worked with Members of Congress and leading academic researchers to craft a bill which would leverage federal resources to improve the development of functional GI and motility disorders treatment options. The time is now to move this important bill forward.
- » **Update** – *The Functional Gastrointestinal and Motility Disorders Research Enhancement Act* was introduced in the House of

Representatives (H.R. 2239) with bi-partisan support. You now have the opportunity to advocate for passage of this landmark bill. (See page 4.)

- **Including “Functional GI Disorders” within Department of Defense (DOD) Medical Research Activities.** Military service, particularly deployment and combat situations, has been linked through medical literature to the onset of functional GI disorders. The Department of Veterans Affairs recognizes functional GI disorders as connected to military service for the purpose of disability. It is for these reasons that DOD through its Congressionally Directed Medical Research Program should support research into functional GI disorders. Members of Congress must work to see that DOD takes on these research activities.

» **Update** – The Senate Appropriations Committee September 2011 report “recognizes the direct link between functional gastrointestinal disorders, such as irritable bowel syndrome and functional dyspepsia, and gulf war syndrome, as detailed in the *Institute of Medicine report Gulf War and Health: Volume 8. Health Effects of Serving in the Gulf War*. The Committee urges the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) to collaborate with the Department of Defense and the Department of Veterans Affairs to advance research on the etiology, natural history and quality of functional gastrointestinal disorders in patients with gulf war syndrome. *Ask your Senators to ensure that “Gulf War Illness” is funded in the Department of Defense (DOD) Peer-Reviewed Medical Research Program (PRMRP) within the FY 2012 Defense Appropriations Bill.*

- **Re-Introduction and Passage of the Pediatric Consortium Establishment Act.** This Act would establish 20 federally supported pediatric research consortia through NIH and fund them at up to \$2.5 million per year. In the last Congress, this bill almost became law; it was passed by the House and nearly passed the Senate. This funding could potentially benefit pediatric functional GI and motility disorders research in a number of areas. Our own Children’s GI Research Network would be a candidate for funding if this bill is enacted. Members of Congress must work to pass this bill as quickly as possible.

» **Update** –The Senate Appropriations Committee September 2011 report “urges NIDDK to work with the National Institute of Child Health and Human Development (NICHD) to support research on the quality of life for children suffering from FGIDs, which often interfere with emotional, social and professional development and can impair physical, economic and educational well being.

**Here is how you can participate . . .**

- Become a grassroots advocate
- Use your story to build a relationship with your Members of Congress
- Urge them to take action on these issues

All of the above legislative priorities need your support to secure passage in the House and Senate. If you would like to become an advocate and join others in coordinated congressional outreach activities as part of our nationwide grassroots network, please contact Selena La Porte at [slaporte@iffgd.org](mailto:slaporte@iffgd.org).



## Community News

Find out what is happening in your digestive health community. Raise funding for research, raise awareness about digestive health conditions, or reach out to others.

### Southeastern Wisconsin Regatta

The First Annual DHA Regatta was held on August 20, 2011. Sailors, party-goers, volunteers, advocates, and the Milwaukee Brewers Famous Racing Sausages all enjoyed the day while raising funds for kids GI research. The event was attended by digestive health supporters from Chicago to Milwaukee and points in between. Attendees enjoyed the barbecue lunch, harbor sailboat rides, live music, and games for the children.

Representatives from two of the DHA Children's GI Research Network centers attended the event. Dr. Miguel Saps of Children's Memorial Hospital, and Dr. Manu Sood, of Children's Hospital of Wisconsin, were on hand to help give out awards to the sailors. One of Dr Sood's patients, Amanda Hintz, also attended the event, and was interviewed by the *Kenosha News*.



*Amanda Hintz and Dr. Manu Sood with the Milwaukee Brewers Famous Racing Sausages.*

Amanda, 17, has had gastroesophageal reflux disease (GERD) since birth and chronic intestinal pseudo-obstruction that leave her unable to eat solid food except occasional ice cream.

Amanda, who hopes to go to medical school to be a doctor, has a 4.0 grade average but is behind a year in school due to illness. She receives medication and is fed through a port in her chest.

Her mother, Sonja, who is a nurse, said that taking care of the tube and medication, "is a full-time job, and I'm a nurse." "The pain of this condition is very difficult to control," Amanda said. "The hardest thing is seeing how much you can take of this. The biggest thing they need is research funding. It (her condition) is rare enough that there doesn't seem to be enough awareness."

Nineteen boats participated in the regatta which began as soon as some early storms passed out of the area. Doug Vaccarello and his boat *Sirocco* won the regatta and as well as the Patients' Champion Cup for collecting the most donations. Gary Powell with *Contentious* and Jim Buck with *Rainbow* were the Pickle Boat winners.





**A special thanks to the following sponsors:**

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Weber Grill/ Weber Grill Restaurant

Milwaukee Brewers Baseball Club

Carson's Ribs Restaurants

2-Story Creative

Kenosha Yacht Club

Ron & Kathy Otto

Kenosha Community Sailing Center

Great Lakes Distillery

Vielle & Frances

Cruzan Rum

Fluid Equipment Sales

Vineyard Vines

Elements East

Gruvy Wear

Pro Source Wholesale Floor

Bakery On Main

Pfister Hotel

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