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INTERNATIONAL FOUNDATION FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

Congressional Record

Proceedings and Debates of the U.S. Congress

APRIL IS IBS AWARENESS MONTH

HON. JAMES P. MORAN OF VIRGINIA

IN THE HOUSE OF REPRESENTATIVES

Tuesday, April 29, 2014

Mr. MORAN. Mr. Speaker, I rise today to recognize April as IBS Awareness Month. Irritable bowel syndrome, or IBS, is a functional gastrointestinal disorder. It is characterized by recurring abdominal pain or discomfort related to changes in intestinal function. Other GI symptoms, such as nausea or bloating, and non-GI symptoms, such as sleep disturbances or headache, may often occur. IBS affects up to 15 percent of the U.S. population and accounts for roughly 40 percent of all referrals to gastroenterologists.

There is no cure and there are few treatments options for IBS, many of which are only marginally effective. Individuals with moderate to severe IBS struggle with symptoms that significantly limit their physical, emotional, economic, and social well-being. For example, a recent study found that employees with IBS had higher average total healthcare costs, and significantly higher medically related work absenteeism.

People of all ages are affected by IBS. One study found that 14 percent of high school students and six percent of middle school students have IBS. Children with IBS are also more likely to experience anxiety and depression and a disruption of normal activities and social interactions. In addition, veterans and active military personnel are disproportionately represented by those suffering from IBS and other functional gastrointestinal disorders due to their exposure to increased risk factors.

I am encouraged by efforts by non-profits to provide education, support, and advancing research. Recently, the International Foundation for Functional Gastrointestinal Disorders (IFFGD) developed a smart-phone app that allows patients to access information on IBS, including treatment options. These are the kind of new initiatives that need advancing so that the millions of Americans with IBS can be treated more effectively.

I urge my fellow Members of Congress to support research efforts and to raise awareness for IBS. As an institution, let's agree to lessen the stigma for IBS patients and urge those who may be affected by IBS to find out more and get the help they need.

In the final days of IBS Awareness Month 2014, Representative Moran entered this statement in the U.S. House of Representatives. His remarks speak to the challenge that all people with IBS face, including children and veterans. Congressman Moran also highlighted the new mobile app from IFFGD, *IBS Info*, and encouraged his colleagues in Congress to "support research efforts to raise awareness for IBS."

Congressman Moran's statement is recorded in the *Congressional Record*, the official record of the proceedings and debates of the U.S. Congress, published by the U.S. Government Printing Office.

We are grateful that Rep. Moran took this action on behalf of the IBS community. It is an added step to help raise awareness on Capitol Hill, among regulators and those and appropriate and allocate funding for research, about IBS.

Thank you Congressman Moran.

The Use of Probiotics in Managing Gastrointestinal Symptoms

Probiotics are defined as live microorganisms, which when administered in adequate amounts, confer a health benefit on the host.

There is a growing interest in finding out if probiotics can be used to help relieve symptoms of functional gastrointestinal (GI) and motility disorders. The variety of products, and claims for their usefulness, is increasing.

Probiotics, for example bacteria, are either the same as or similar to microorganisms found naturally in the human body and (in adequate amounts) may be beneficial to health. Also referred to as "good bacteria" or "helpful bacteria," probiotics are available to consumers in oral products such as dietary supplements and yogurts, as well as other products.

About Probiotics

The concept behind probiotics was introduced in the early 20th century, when it was proposed that ingesting microorganisms could have substantial health benefits for humans. Scientists continued to investigate the concept, and the term probiotics – meaning "for life" – eventually came into use.

Picturing the human body as a "host" for bacteria and other microorganisms is helpful in understanding probiotics. The body, especially the lower GI tract (the gut), contains a complex and diverse community of bacteria. In the body of a healthy adult, cells of microorganisms are estimated to outnumber human cells by a factor of ten to one. Although we tend to think of bacteria as harmful "germs," many bacteria actually help the body function properly.

Various mechanisms may account for the effects of probiotics on human health. Possible mechanisms include reducing harmful organisms in the intestine, producing antimicrobial compounds (substances that destroy or suppress the growth of microorganisms), and stimulating the body's immune response.

Probiotics commonly used in the United States include *Lactobacillus* and *Bifidobacterium*. There are many specific types of bacteria within each of these two broad groups, and health benefits associated with one type may not hold true for others.

Although the U.S. Food and Drug Administration (FDA) has *not* approved any health claims for probiotics, they are used for a variety of GI conditions such as infectious diarrhea, diarrhea associated with using antibiotics, irritable bowel syndrome (IBS), and inflammatory bowel disease (e.g., ulcerative colitis and Crohn's disease). However, the rapid growth in marketing and consumer interest and use has outpaced scientific research on the safety and efficacy of probiotics for specific health applications.

Ten leading European gastroenterologists conducted a review of the evidence for the use of specific probiotics in managing certain lower GI problems. Their findings were published in 2013 in the peer-reviewed journal, *Alimentary Pharmacology and Therapeutics* (Higgins, *et al*.).

The systematic review of randomized, placebo-controlled clinical studies on probiotics in adults looked mostly at studies of IBS patients. The authors sought to determine the level of available evidence to support the use of specific probiotics in adults. The findings are not applicable to children because the bacteria found in their gut differ from adults.

Among the conclusions, the authors found moderate evidence to support a role for specific probiotics in managing overall symptoms in patients with IBS with diarrhea; improving bowel movements and bloating or distension in patients with IBS; and improving some aspects of health-related quality of life.

The authors note that these findings are specific to individual strains or formulations of probiotics and cannot be applied from one probiotic to another. Moreover, specific probiotics will have different effects in different people; and a probiotic may show some benefit for one indication but not for another. Your age and health status when taking a probiotic will affect its potential benefit. They also note, when trying a probiotic for a chronic GI problem, the importance of taking the product:

- In adequate doses
- On a regular basis
- For a reasonable period (of at least a month unless it cannot be tolerated)

Different formulations and doses are available in capsules, packets/sachets, yogurts, and fermented milks or fruit drinks. While research is supporting positive evidence for a role of probiotics in managing lower GI problems, clear guidance for specific uses remains to be found. Further studies are needed to establish high levels of evidence for the role of probiotics in treating functional GI disorders as well as other conditions.

What the Science Says

The potential of probiotics to benefit human health in many different ways has stimulated great interest and activity among researchers. For example, the U.S. National Center for Complementary and Alternative Medicine (NCCAM) is part of the National Institutes of Health (NIH) Probiotic and Prebiotic Working Group, a trans-NIH effort to identify gaps and challenges in prebiotic/probiotic research. Trans-NIH collaborations are a way that different areas of NIH work together to maximize resources in order to advance medical research. *(Prebiotics are food ingredients that can selectively promote the growth of "good" intestinal bacteria.)*

Probiotic research is moving forward on two fronts: basic science (laboratory studies) and clinical trials to evaluate the safety and efficacy of probiotics for various medical conditions. Many early clinical trials of probiotics have had methodological limitations, and definitive clinical evidence to support using specific probiotic strains for specific health purposes is generally lacking. Nevertheless, there is preliminary evidence for several uses of probiotics, and more studies are under way.

Safety and Side Effects

It appears that most people do not experience side effects from probiotics or have only mild GI side effects, such as gas. But there have been some case reports of serious adverse effects, and research on safety is ongoing. However, the data on safety, particularly long-term safety, are limited, and the risk of serious side effects may be greater in people who have underlying health conditions.

Concerns have also been raised about the quality of probiotic products. Some products have been found to contain smaller numbers of live microorganisms than expected. In addition, some products have been found to contain bacterial strains other than those listed as ingredients.

If You Are Considering Probiotics

- Before using probiotics, learn as much as you can by talking to your provider and researching reliable sources of information.
- Probiotic products may contain different types of probiotic bacteria and have different effects in the human body. The effects also may vary from person to person.
- Do not replace scientifically proven treatments with unproven products and practices. Do not use a complementary health product, such as probiotics, as a reason to postpone seeing your healthcare provider about any health problem.
- If you are pregnant or nursing a child, or if you considering giving a child a dietary supplement, such as probiotics, it is especially important to consult your (or your child's) healthcare provider.
- Anyone with a serious underlying health problem should be monitored closely for potential negative side effects while taking probiotics.
- Tell all your healthcare providers about any complementary health approaches you use. Give them a full picture of what you do to manage your health. This will help ensure coordinated and safe care.

This article was adapted from: National Center for Complementary and Alternative Medicine, *Oral Probiotics*. NCCAM Pub #D345, 2012. ■

PROBIOTICS MUST BE TESTED IN HUMANS AND SHOWN TO HAVE HEALTH BENEFITS. Here are some tips to help you find a credible probiotic product, from the International Scientific Association for Probiotics and Prebiotics *(www.isapp.net)*

Clinically proven: Do your homework – Make certain that product claims of health benefits are based on sound research done on the particular probiotic. The product should contain the specific strain(s) of bacteria at the same levels as used in published research. The studies should be performed in humans and published in peer-reviewed, reputable journals. Check product websites to see study results. Your pharmacist or healthcare provider should be able to help you sort through the scientific language.

Claims: What do they mean? – Most probiotics are sold as dietary supplements or ingredients in foods, and cannot legally declare that it can cure, treat or prevent disease. Claims which relate the product to health are allowable. Any claim made on a product, no matter how general, is supposed to be truthful and substantiated – but not all manufacturers have this clinical substantiation.

Get your doctor's OK – Consult a physician before administering probiotics to newborns or infants, or to people with compromised immune systems or other major underlying illnesses. Read "Warnings" and "Other Information" on the product package and be aware of any expected symptoms or side effects. Probiotic foods should be safe for the generally healthy population to consume.

More information – The product you choose should offer resources to find more information, including a website or consumer hotline.

Remember, some products labeled "probiotic" do not have clinically validated strains or levels in the product. Although the scientific definition of probiotic stipulates that products be clinically evaluated, not all manufacturers abide by that.

Medical News Update

Higher Prevalence of Celiac Disease among Children with IBS

A study published recently in the journal *JAMA Pediatrics* found a 4-fold increased incidence of celiac disease among children with irritable bowel syndrome (IBS), but not in children with other functional abdominal pain conditions. This is similar to a recent finding in adults.

Results showed that 4% of the children with IBS tested positive for celiac disease, compared with 1% or less of those with functional dyspepsia and with functional abdominal pain.

Because it has become routine to test for celiac disease in all children with recurrent abdominal pain, limiting celiac screening only to those with IBS may be beneficial. It may reduce unneeded testing in children who are no more likely than the general population to have celiac disease, and it could reduce the health consequences for children with IBS who also have untreated celiac disease.

Less Aggressive Treatment May Be Warranted for Many Cases of Diverticulitis

Recently *JAMA* published a review of medical studies about diverticulitis that have been published over the past decade. The review suggests that changes be made in the way the disease is often treated. Diverticulitis occurs when small pouches in the GI tract become infected.

The reviewers observed advances in the understanding of diverticulitis, which warrant less frequent use of antibiotics and surgery. Among the findings were that the risk of recurrence of diverticulitis is low, and the risk of abdominal infection decreases with each recurrence.

Small Intestinal Bacterial Overgrowth In Gastroparesis

A study has shown that small intestinal bacterial overgrowth (SIBO) can be somewhat common in those with gastroparesis.

In a study of 740 patients who were tested for SIBO, 39% of those who had gastroparesis tested positive. Overall, no significant difference in gastroparesis symptom severity was seen between positive and negative results in those with gastroparesis, but there was increased severity of bloating and excessive fullness during and after meals.

Survey – Many Want Medication to Treat Celiac Disease

Many people suffering from celiac disease are interested in potential medications to treat the condition, according to a published survey that measured the impact of celiac disease on a person's life. Currently, a gluten-free diet is the only treatment for celiac disease.

Survey responses were analyzed from 352 patients with celiac disease. When asked if they would take a medication to treat the condition, interest was highest among men, older respondents, frequent restaurant customers, those dissatisfied with their weight or concerned with the cost of a gluten-free diet, and those with a worse quality of life. Length of time since diagnosis and response to a gluten-free diet did not appear to increase interest in using medication.

Salmonella Gastroenteritis During Childhood is a Risk Factor for Irritable Bowel Syndrome in Adulthood

Based on data collected from a single foodborne *Salmonella* outbreak, researchers have shown that *Salmonella*-induced gastroenteritis during childhood (but not adulthood) is a risk factor for IBS. The outbreak, which occurred in 1994 in Bologna, Italy, involved mostly children.

Clinical data were collected and long-term effects were assessed by mailing a questionnaire to 757 subjects, 16 years after the outbreak (when all of children were adults).

The prevalence of IBS was higher in individuals exposed to *Salmonella* as children, but not as adults, compared with controls. Preventive measures early in life may help reduce the risk of IBS in adulthood.

Researchers Find Genetic Clue in Irritable Bowel Syndrome

A group of researchers studying a specific genetic defect concluded that about 2% of people with IBS carry a mutation in the SCN5A gene. This defect affects a mechanism involved with maintaining normal gastrointestinal motility. The research is in early stages, but the results of this study give researchers hope of finding new therapies for this subset of people with IBS.

This work was supported by grants from the NIH, Mayo Clinic, and the Swedish Research Council.

Small Particle Size Diet Helps Those with Diabetic Gastroparesis

A randomized controlled trial examined the effect of an experimental diet in people with diabetic gastroparesis, and found that a small-particle size diet may relieve upper GI symptoms.

Dietary restriction is required to treat both gastroparesis and diabetes. This study tested a usual diet for diabetes versus a nutritionally identical experimental diet, which differed regarding the particle size of the food. This was described as food that was "easy to mash with a fork into small particle size." Foods with husks or peels; seeds and grains; or poorly digestible particles such as meat, raw vegetables, and pasta were excluded.

GI symptoms such as nausea/vomiting, early fullness, and bloating were all reduced in those who received the small-particle diet. Nutrient intake, glycemic control, and quality of life were the same in both diets. Longer studies may be needed to test these findings.

This is the first randomized controlled study of a diet for diabetic gastroparesis. The 20-week study included 56 adults with insulin treated diabetes and gastroparesis.

The Role of the Gut Microbiota in IBS and Bloating

"Recent findings suggest that IBS is linked to clearly detectable gut microbiota alterations. Additionally, bloating can be related to specific kinds of diet, thus opening up promising paths towards an efficient disease management," says Professor Giovanni Barbara (University of Bologna, Italy). This was one of the topics presented at the Gut Microbiota for Health World Summit in Miami, Fla., USA on March 8 and 9, 2014.

"Probably the best example of this interaction is the discovery that IBS symptoms develop in up to 10 percent of previously healthy subjects after a single episode of gastroenteritis caused by an infection through bacterial pathogens, which can severely disrupt the microbiota balance," says Professor Barbara.

Another important factor is nutrition. Studies show that certain foods can induce changes in the microbiota of IBS patients, prolonging and increasing the symptoms, while the gut microbiota of healthy subjects remained stable and unaffected.

Read more about Post-Infectious IBS at *http://www.aboutibs.org/site/what-is-ibs/intro-to-ibs/post-infectious-ibs*.

Early Research Suggests IBS may Sometimes be Associated with Maternal Inheritance

A small pilot study may show that some IBS is hereditary, and linked to DNA in the cells of the mother. By analyzing the mitochondrial DNA of patients with IBS, IBD, and healthy controls, scientists found probable maternal inheritance in 17.5% of the people with IBS, compared to only 2% of otherwise healthy people and 0% the people with IBD.

Mitochondria are important structures inside our cells, and in humans are inherited only from the mother. Mitochondrial dysfunction has been implicated in disorders that often co-occur with irritable bowel syndrome, such as migraine, depression, and chronic fatigue syndrome. These findings suggest that about one person in six with IBS could have an IBS subtype related to mitochondrial function, and that further research in this area is warranted.

MRI Modeling Revealed Abnormal Anatomical Structure in Those with GERD

A small study has demonstrated that magnetic resonance imaging (MRI) technology can reveal anatomical and functional differences between people with GERD and those without. The differences affect the normal way in which the esophageal and gastric (stomach) anatomy acts to prevent reflux.

The findings demonstrate in a non-invasive testing situation that the "functional anatomy" which normally helps provide a barrier to reflux, is altered in people with mild to moderate GERD. This helps to better understand the mechanisms by which reflux is normally prevented, as well as the changes which allow it to occur.

New Drug Application Submitted in Japan for the Treatment of Acid-related Diseases

Takeda Pharmaceuticals has announced that they have submitted a new drug application (NDA) in Japan for a new class of drug to treat acid-related disorders. The compound has been assigned the generic name vonoprazan fumarate. It belongs to a new class of acid secretion inhibitors called potassium-competitive acid blockers. They work slightly differently from proton-pump inhibitors (PPIs), which are currently among the most common treatments for these disorders.

The NDA was submitted based on positive results from Phase III clinical trials in Japan, for indications including erosive esophagitis, gastric ulcer, duodenal ulcer, and *H. pylori* eradication.

Capsule Bowel Prep in Development

Salix Pharmaceuticals is partnering with another company to develop a bowel prep compound that is in the form of a tasteless capsule. Currently, people preparing for abdominal procedures or diagnostic tests such as colonoscopy must drink a bowel prep solution to help cleanse the gastrointestinal tract. Most liquid preparations require drinking a large quantity of the prep which many people find unpleasant to the taste. The RHB-106 preparation is a solid capsule which eliminates any unpleasant taste and could potentially make it easier for people to use.

Researchers Discover Mechanism of Movement in the Bowels

Researchers led by a group at McMaster University in Canada have discovered a mechanism that helps us better understand how the bowels function. The finding may lead to a better understanding of how to treat people with disorders of nutrient absorption, diarrhea, constipation, and bloating.

Food in the intestine must be propelled along the gut from the stomach down to the colon (a movement referred to as peristalsis), and it also must be mixed to maximize the absorption of nutrients.

The mechanism of peristalsis has previously been demonstrated to be the result of a slow-wave pacemaker generated by special cells in the intestinal walls, called interstitial cells of Cajal (ICCs).

The researchers discovered that the mixing movement is generated by a second pacemaker that interacts with the first. Together, they create back and forth movements that optimize nutrient absorption. ■

Medical News from

The following medical studies were presented as abstracts at the May 2014 Digestive Disease Week (DDW), a conference for medical professionals. They indicate new findings of possible treatments. However, the data and conclusions should be considered preliminary until the data is published in a peer-reviewed journal.

Prescription Medical Food Neutralizes *C. difficile* Toxins

New data using laboratory models examining the prescription medical food, EnteraGam™, was presented at DDW, demonstrating that the protein mixture in EnteraGam binds and neutralizes two types of toxins from several types of *C. difficile*, including recently isolated strains which are particularly infectious.

The laboratory based data specifically showed direct binding of immunoglobulins in EnteraGam to each toxin, as well as protection from cell death of cells which are particularly affected by toxins. *C. difficile* toxins can cause damage to the lining of the intestines, contributing to the symptoms of infection that can range from diarrhea to severe, life-threatening colitis.

Novel Drug for Celiac Disease Reduces GI and Non-GI Symptoms

A novel drug designed for the treatment of celiac disease reduced both gastrointestinal (GI) and non-GI symptoms in people exposed to gluten, in a randomized placebo-controlled trial presented at DDW.

Larazotide acetate is a first-in-class oral peptide which affects intestinal barrier function and reduces gluten uptake, inhibiting gluten-induced intestinal permeability and inflammation.

Celiac disease, which is triggered by the ingestion of gluten, is managed with a gluten-free diet. However, symptoms often recur as a result of accidental exposure to gluten or not strictly following the diet. Recently published data suggest that 70% of patients continue to be exposed to gluten while on a gluten-free diet. This exposure causes not only GI-related symptoms, but also non-GI symptoms such as headache and tiredness. Larazotide acetate reduced both types of symptoms in this trial.

Digestive Disease Week 2014

Larazotide acetate has the potential to be the first pharmacologic treatment for celiac disease and warrants investigation in Phase 3 clinical trials, the study author concluded. The drug has been granted Fast Track status by the U.S. Food and Drug Administration.

Investigational Drug Shows Promise in Diabetic Gastroparesis

The investigational drug RM-131 (relamorelin) significantly improved gastric emptying and vomiting in patients with diabetic gastroparesis in a Phase 2, double-blind study presented at DDW.

Gastric emptying improved by an average of 23 minutes from baseline, and also reduced vomiting episodes and vomiting severity, when taken by twice-daily injection for four weeks. Ghrelin is a hormone produced in the stomach that stimulates gastrointestinal activity. Relamorelin promotes activity of ghrelin.

Brush Biopsy Increases the Detection of Barrett's Esophagus

A study presented at DDW shows that a procedure using a computer-assisted technique where a brush collects a tissue sample (biopsy) may be better at detecting Barrett's esophagus than the traditional forceps biopsy method. Barrett's esophagus, a condition marked by cellular changes, is a risk factor for esophageal cancer.

Investigators reviewed data on patients who underwent endoscopy for the evaluation of gastroesophageal reflux disease from 28 community based gastroenterologists. Both brush biopsy samples and forceps biopsy samples were collected on each patient during the same endoscopy procedure.

Forceps biopsy identified Barrett's esophagus in 377 cases and the computer assisted brush biopsy identified an additional 258 cases, enhancing the detection of Barrett's esophagus by 68.4%. The authors conclude that this technique, used by community gastroenterologists, may help improve care by better identifying these patients.

Low FODMAP Diet May Help Children with IBS

A small, short-term diet low in certain types of poorly absorbed and highly gas-forming carbohydrates (FODMAPs) may reduce symptoms in children diagnosed with irritable bowel syndrome (IBS), according to an abstract presented by researchers at DDW. In the nine-day study, children had fewer daily abdominal pain episodes, as well as less bloating and nausea, during the two-day periods on which they ate low-FODMAPs.

Additional studies are underway to further explore the efficacy of low-FODMAP diets and how they interact with other existing factors.

FODMAPs are found in many fruits, vegetables, dairy products, and sweeteners. Find out more about FODMAPs on our website *aboutIBS.org*.

Use of Lincalotide Reduces Bloating, Improves Health Related Quality of Life

Research summaries presented at DDW reviewed data from Phase 3 and Phase 3b clinical trials of linaclotide (Linzess) in people with chronic constipation.

New data from a Phase 3b trial showed that linaclotide improved bowel and abdominal symptoms, in those with chronic idiopathic constipation with prominent bloating at the start of the trials.

Data from two Phase 3 trials was pooled to review the relationship between chronic constipation symptoms, and health-related quality of life (HRQOL). The study concluded that reduction in bloating was more strongly associated with improved HRQOL than other chronic constipation symptoms. ■

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.

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Linaclotide (Constella) Available in Europe for Treatment of IBS-C

Linaclotide is the first medicine approved by the European Commission for the symptomatic treatment of moderate to severe irritable bowel syndrome with constipation (IBS-C) in adult patients. It is currently available in several European countries with the EU brand name Constella.

Linaclotide, a guanylate cyclase type-C (GC-C) agonist, is a prescription drug used to relieve symptoms of abdominal pain, discomfort, bloating, and bowel symptoms in people who have IBS-C or chronic constipation (CC). It has been shown to be safe and effective in trials. It works by increasing the amount of fluid that flows into the bowel, allowing stool to pass more easily, and reducing visceral pain.

Linaclotide (Linzess) has been available in the U.S. to treat IBS-C and CC in adults aged 18 and older since 2012. The safety and effectiveness of Linzess for the management of IBS-C were established in two, double-blind studies in which a total of 1,604 patients were randomly assigned to take Linzess or a placebo for at least 12 weeks. Results showed Linzess was more effective in reducing the amount of abdominal pain and increasing the number of complete spontaneous bowel movements compared with placebo.

Linzess should *not* be used in patients 17 years of age or younger. Linzess should *not* be used in patients with known or suspected mechanical gastrointestinal obstruction. The most common side effect reported during clinical studies was diarrhea.

Linaclotide is being co-produced in the U.S. by Ironwood Pharmaceuticals and Forest Laboratories. Ironwood has out-licensed linaclotide to Almirall, S.A. for development in Europe; and to Astellas Pharma for development in Japan, Indonesia, Korea, the Philippines, Taiwan, and Thailand.

Medical Food in the Management of Diarrhea

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

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

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

Study Evaluates Impact of SBI in People with Diarrhea-Predominant IBS

Results from a randomized, double-blind, placebo-controlled pilot study enrolling 66 subjects suggest that nutritional therapy with SBI, the ingredient found in EnteraGam – used in addition to traditional medical care – can help manage various symptoms associated with irritable bowel syndrome with diarrhea (IBS-D). The study, by Wilson *et al.*, was published in 2013 in the journal, *Clinical Medicine Insights: Gastroenterology*.

A total of 45 persons completed the study per the protocol, with 31 in the SBI group and 14 in a placebo group. The symptom profile of each participant was determined during the first week, followed by a six-week treatment period. Of the subjects who did not complete the study, five were lost to follow-up, three did not comply with the study requirements, one discontinued due to lack of efficacy, and two were removed at the Principal Investigator's discretion. The safety profile of SBI in the study was similar to that of placebo. A total of four people withdrew, from both the placebo and the SBI groups, due to nausea. No serious adverse events were reported. The proportion of subjects who withdrew was not significantly different between treatment groups.

The study showed that nutritional therapy with either 10 g/day or 5 g/day of SBI in patients was well tolerated and resulted in statistically significant improvements in days with symptoms and a trend for improvement in symptom severity scores in participants with IBS-D. In particular, the 15 participants who received 10 g/day of SBI showed significant reductions in abdominal pain, loose stools, bloating, flatulence, and urgency.

The product has been extremely well tolerated for up to a year in HIV patients and up to eight months in infants. The major side effects in clinical trials (2–5%) have included mild nausea, constipation, stomach cramps, headache, and increased urination. EnteraGam is contraindicated for patients with a hypersensitivity (allergy) to beef, or any components in EnteraGam. Therefore, patients who have an allergy to beef or any component of EnteraGam should *not* take this product. The effect of EnteraGam on nursing mothers and the infant is unknown. The choice to administer EnteraGam in pregnant or nursing mothers is up to the clinical decision of the physician. Medical foods like EnteraGam are required by the U.S. Food and Drug Administration (FDA) regulations to be dosed and monitored by physicians as part of ongoing care for patients with chronic conditions or diseases.

EnteraGam is manufactured and distributed by Entera Health, Inc.

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

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

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

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

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

Data from a two-year study by NPS Pharmaceuticals supports the long-term use of Gattex for injection in adult patients with short bowel syndrome (SBS). The findings were published as an abstract and presented at the American College of Gastroenterology (ACG) Annual Scientific Meeting and Postgraduate Course in San Diego, CA in October 2013. Patients in the study using Gattex beyond one year continued to be able to reduce their support on parenteral nutrition.

The open-label extension study included 88 adult patients with SBS. Investigators reported that the long-term use of Gattex in patients with SBS resulted in additional, clinically meaningful reductions in the volume and days per week of parenteral support requirements in this extension study. Thirteen patients in the study achieved complete independence from parenteral support with long-term Gattex therapy. No new unexpected safety concerns were observed with long-term Gattex treatment and the product's safety profile remains consistent with the product's label.

The drug works by regeneration of cells in the intestinal lining, slowing down transit through the gut and increasing blood flow, allowing for increased nutrient absorption. In studies, the drug was associated with

achieving and maintaining clinically meaningful reductions in parenteral nutrition (PN) and intravenous (IV) fluid volume in adult subjects with SBS.

Gattex was approved by the U.S. Food and Drug Administration (FDA) in 2012 for treatment of adult patients with SBS who are dependent on parenteral support. To help ensure that the benefits of Gattex outweigh the risks for causing other serious conditions, the drug is approved with a Risk Evaluation and Mitigation Strategy, which patients need to discuss with their doctors. While the researchers found the safety profile to be acceptable, they advise that physicians closely monitor patients beginning the drug for side effects and possible need to adjust dosage.

SBS is a rare condition related to poor absorption of nutrients. It typically occurs in people who have a significant portion of their small intestine removed due to disease or injury. They cannot absorb enough water, vitamins, and other nutrients from food and may need to use parenteral nutrition and intravenous fluids.

Seeking Participants for Study to Assess Teduglutide as Treatment for Pediatric Short Bowel Syndrome

This 12-Week, open label study will evaluate the effectiveness and safety of teduglutide as a treatment for pediatric patients with short bowel syndrome on parenteral support.

Sponsored by:
NPS Pharmaceuticals, Inc.

Participation: Eligible male and female patients aged 1-17 years.

Contacts: Clinical Operations, 908-450-5300, *info@npsp.com*; Be sure to refer to this study by its ClinicalTrials.gov identifier: NCT01952080

Participants Sought for a Long-term Study of Patients with Short Bowel Syndrome (SBS)

This global clinical study has begun enrolling patients with SBS in order to provide additional long-term data on safety of teduglutide and on the natural history of SBS in patients in routine, real world settings. The information gathered is intended to assist health care providers in optimizing their clinical decision-making in managing SBS patients. Enrollment will include SBS patients treated and not treated with teduglutide.

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

Study Follow-up Duration:
10 years

Sponsored by:
NPS Pharmaceuticals, Inc.

Contact: NPS Clinical Operations:
908-450-5300 Email:
SBSregistry@quintiles.com

Relistor Being Reviewed for Treatment of Opioid-Induced Constipation in Europe

In late April 2014 Salix Pharmaceuticals announced their submission for the medication Relistor had been accepted for review by the European Medicines Agency. Their submission asks to allow the use of Relistor for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain. The European Union already allows the use of Relistor in patients with advanced illness.

Rifaximin Studied for Treatment of Non-Constipation IBS

Rifaximin is an antibiotic currently under investigation for the treatment of non-constipation IBS (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 after a 10–14 day course of treatment. It is only slightly absorbed in the gut and is generally tolerated well. Rifaximin has not yet been approved by the U.S. Food and Drug Administration (FDA) for the treatment of IBS.

Solesta Available in the U.S. to Treat Bowel Incontinence

Solesta, a biocompatible tissue bulking agent, was approved by the U.S. Food and Drug Administration (FDA) for the treatment of bowel incontinence in patients 18 years and older who have failed conservative therapy (e.g., diet, fiber therapy, anti-motility medications). The drug has been approved to treat bowel incontinence in the U.S. since 2011 and in Europe since 2006. Bowel 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.

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. It should only be administered by physicians who are experienced in performing anorectal procedures and have successfully completed a comprehensive training and certification program

in the Solesta injection procedure. 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. In December 2011 Salix Pharmaceuticals, Ltd. acquired all of the outstanding stock of Oceana Therapeutics, Inc.

Lubiprostone Study Published Showing Efficacy in Opioid-Induced Constipation (OIC)

A study published in the medical journal *Pain Medicine* examined the efficacy and safety of lubiprostone (Amitiza) for relieving symptoms of opioid-induced constipation (OIC) in chronic non-cancer pain. The study found that patients treated with lubiprostone showed significant overall improvement for abdominal discomfort, straining, constipation severity and stool consistency when compared to placebo. The authors concluded that lubiprostone effectively relieved OIC and associated signs and symptoms and was well tolerated in OIC patients with chronic non-cancer pain.

In April 2013 Sucampo Pharmaceuticals and Takeda Pharmaceuticals U.S.A. announced that the U.S. Food and Drug Administration (FDA) approved the supplemental New Drug Application for lubiprostone to treat opioid-induced constipation in adult patients with chronic non-cancer pain. The drug was approved to treat chronic idiopathic constipation (CIC) in adults in 2006 and to treat IBS with constipation (IBS-C) in adult women in 2008.

Amitiza is a prescription drug used to relieve abdominal pain, bloating, and straining and produce softer and more frequent bowel movements in men and women who have CIC. It is also used to treat 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.

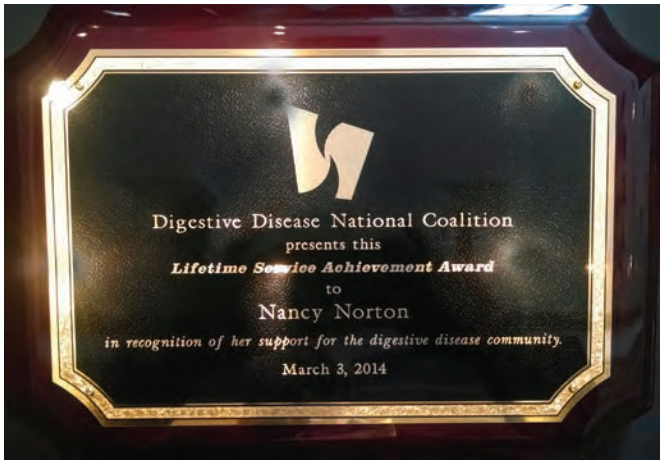
The drug met the primary endpoint in a Phase 3 clinical trial for the treatment of opioid-induced bowel dysfunction in patients with chronic, non-cancer pain, excluding those taking methadone. Opioids are narcotics (such as morphine and codeine) used to treat pain. A number of gastrointestinal (GI) symptoms are potential side effects of using opioid-based medications. The most common symptom is constipation. Other symptoms may include decreased gastric emptying, abdominal cramping, spasm, bloating, and delayed-GI transit. ■

IFFGD President Honored at 2014 DDNC Public Policy Forum

In March, 2014 IFFGD traveled to Washington, D.C. for the 24th Annual Digestive Disease National Coalition (DDNC) Public Policy Forum. There we joined with patients, organizations, physician societies, industry partners, lawmakers, and their legislative staff for two days of legislative updates and advocacy activities. This also provided us with another opportunity to meet with Members of Congress from across the nation and urge their support on issues of concern to the digestive disease community, including scientific research, patient care, prevention, and public awareness.

One of the highlights of the event was the Awards Luncheon, where the DDNC presented IFFGD Founder and President Nancy Norton with the DDNC Lifetime Service Achievement Award in recognition of her continued service to the digestive disease community.

Nancy served for many years as the DDNC's Chairperson and is dedicated to the DDNC mission to improve patient access to digestive health care. She was honored to receive the award and said, *"The DDNC has provided a vehicle to bring issues to Members of Congress for so many patient organizations that otherwise may not have had an opportunity to participate on the federal level. Our efforts today in Washington give voice to the needs of patients and the ongoing struggles faced when living each day with a digestive disease. We see medical progress being made in all areas of digestive disease research yet we still have a long way to go. The DDNC provides the opportunity for us to speak with a unified voice and work together toward common goals."*



Digestive Disease Week 2014

Digestive Disease Week is the world's largest meeting of physicians and researchers in the field of gastroenterology, gastrointestinal surgery, and other related fields. We are pleased to share the perspective of patients and others affected by functional GI and motility disorders with healthcare professionals at the meeting each year, as well as hear about the latest advancements in the GI field. Read more about the studies presented at DDW on page 8.

UNC Patient Day

On June 21–22, 2014, we attended a special event in Washington, D.C. put on by the University of North Carolina (UNC) School of Medicine. The two-day symposium was an educational event about functional gastrointestinal (GI) disorders. It gave patients and other interested individuals the opportunity to hear about the current state of treatments and understanding on these conditions from top U.S. experts in the field.

Presenters at the event included IFFGD Advisory Board Members William Whitehead, Ph.D. (who also hosted the event), Lin Chang, M.D., Douglas A. Drossman, M.D., and P. Jay Pasricha, M.D. They were joined by several leading healthcare professionals to discuss issues related to those affected by functional GI disorders, from new approaches to gastroparesis, nausea, and cyclic vomiting; to managing irritable bowel syndrome; to how to make the most of your doctor visit.

We appreciated the opportunity to attend these important events and will continue to keep you informed about the latest knowledge and news from the functional GI and motility disorders field.

Upcoming Events

Behavioral and Rehabilitation Treatment of Bowel Disorders – An Advanced Course
October 16–18, 2014, Milwaukee, WI
www.marquette.edu

2014 ACG Annual Scientific Meeting and Post Graduate Course
October 17–22, 2014, Philadelphia, PA
www.gi.org | Visit IFFGD at Booth #1139!

2014 NASPGHAN Annual Meeting and Post Graduate Course
October 23–26, 2014, Atlanta, GA
www.naspghan.org

DIGESTIVE HEALTH ALLIANCE

DHA Legislative Agenda

National Institutes of Health (NIH)

Overall Investment in NIH: We support increasing **funding for NIH to a level of at least $32 billion in fiscal year 2015 (FY15)**. The bulk of federally supported functional gastrointestinal and motility disorders (FGIMDs) research is conducted through the National Institute of Diabetes, and Digestive, and Kidney Diseases (NIDDK). Increased support for NIH will enable NIDDK and other Institutes and Centers to continue to expand the FGIMD research portfolio and initiate critical new research activities focused on improving our understanding of these conditions and leading to the development of innovative treatment options.

The *Functional Gastrointestinal & Motility Disorders Research Enhancement Act* (H.R. 842)

Support the *Functional GI and Motility Disorders Research Enhancement Act*: This critical piece of legislation seeks to advance our scientific understanding of FGIMDs and improve treatment options for patients by encouraging and bolstering research. This bill calls on NIH to adopt and implement the FGIMD-related research recommendations outlined by *the National Commission on Digestive Diseases*. In addition, this bill calls on NIH to partner with the Department of Defense (DOD) and the Department of Veterans Affairs (VA) to increase research activities. IFFGD urges Members of Congress to champion FGIMD research by becoming a House of Representatives cosponsor or Senate sponsor of the *Functional GI and Motility Disorders Research Enhancement Act*.

National Pediatric Research Network Act (P.L. 113-55)

Support funding for the *National Pediatric Research Network Act*: Many children suffer with painful, disabling, and in some cases life-threatening FGIMDs. Increased pediatric research is needed so that a life-time of discomfort and costly medical treatment can be averted by individuals affected by FGIMDs. This law calls on NIH to establish additional pediatric research consortia. Please work to ensure that this law is implemented with funding for a pediatric FGIMD network.

We'd like to send special thanks to all of you who took time to connect with your Congressional Representatives to ask them to support H.R. 842. So many of you used our automatic email system (*www.iffgd.org/hr842action*), sent postcards for us to hand deliver to your Congressional office, called on Congressional Call-In Day, joined us on Capitol Hill for DHA Advocacy Day, and even took your own trips to talk to Congress about research for functional GI and motility disorders. Thanks for all the hard work. We're ready to do more – are you?!

Washington, D.C. representatives of DHA deliver postcards in support of H.R. 842 to a Congressional Representative's office.

DHA advocates from Pennsylvania on their way to meet with their Members of Congress.

Functional GI Disorders and the Military Service Connection

The onset of a functional GI disorder can be triggered by severe stress and infections of the digestive tract. Deployed military personnel face an elevated chance of experiencing these risk factors and developing a functional GI disorder due to their service. As a result, the VA recognizes a "presumption of service" connection for Gulf War veterans applying for disability who suffer with functional GI disorders. The DOD conducts important research into medical conditions that impact veterans and active duty military personnel through its Congressionally Directed Medical Research Program (CDMRP).

The House and Senate Defense Appropriations Subcommittees fund the DOD CDMRP's Gulf War Illness Research Program (GWIRP), which provides an excellent source of funding for functional GI disorders research. **Legislators must work to see that funding for the GWIRP is included in any agreement on FY15 Defense Appropriations.**

Deployed military personnel face an elevated chance of experiencing risk factors involved in developing a FGID. The relationship between service-related deployment and the onset of a FGID is documented in medical literature, including the 2010 Institute of Medicine report entitled, *Gulf War and Health Volume 8: Update of Health Effects of Serving in the Gulf War.*

Medical Foods and the Food and Drug Administration (FDA)

Medical foods are physician-directed foods intended for the dietary management of a disease or condition that has distinctive nutritional needs that cannot be met by normal diet alone and are used under medical supervision. Many individuals with FGIMDs benefit from medical foods. However, advances in and access to medical foods are now in jeopardy as a result of FDA's 2013 *Guidance for Clinical Investigators, Sponsors, and IRBs: Investigational New Drug Applications (INDs) — Determining Whether Human Research Studies Can Be Conducted Without an IND*, which recommends that medical foods be treated as drugs. The guidance represents a significant expansion of regulation, was published without prior notice or public discussion, is vague, and will inhibit clinical research. **Please ask the FDA for clarification regarding the reasons and purpose for new guidance governing medical foods and request that an open and public process be implemented to consider the needs and impact of any new guidance from FDA in this regard.**

DHA advocates took to Capitol Hill to talk about these important Legislative Agenda items. Since we returned from DHA Advocacy Day, three more Congressional Representatives have signed on as cosponsors of H.R. 842 – Rep. Richard Neal of Massachusetts, Rep. David Price of North Carolina, and Rep. Carol Shea-Porter of New Hampshire!

IFFGD Asks VA to Increase Education, Awareness, and Research for Two Key Issues Related to FGIDs and Military Service

For many years IFFGD has submitted testimony to agencies and committees within the U.S. government, advocating for the needs of those with functional gastrointestinal disorders (FGIDs) and motility disorders. This spring we provided two statements to the U.S. Department of Veterans Affairs (VA) about different aspects of these conditions and how they affect military personnel, both during and following their service.

The VA has helped to recognize the burden of illness of FGIDs, and has taken steps to help relieve that burden. This includes the "Presumptive Service Connection" rule issued by VA in 2011, recognizing the association between service in Southwest Asia during certain periods and the development of FGIDs.

Our most recent statements to VA, in response to their requests for comments, addressed the importance of FGID research related to Gulf War Veterans' Illnesses, as well as the relationship between military sexual trauma and FGIDs.

FGIDs and Gulf War Veterans' Illnesses

Despite the growth of VA's FGID research portfolio in recent years, and their work to advance the understanding of conditions such as irritable bowel syndrome (IBS), additional research is needed in this area to find more and improved treatment options.

In our statement to the VA Research Advisory Committee on Gulf War Veterans' Illnesses, IFFGD made the following suggestions to the committee:

- Streamline logistics set up to harmonize the patient data collected by the Department of Defense (DOD) with data collected by VA.
- Provide investigators with direct access to harmonized patient data and develop assessments for tracking functional GI disorder patients longitudinally to understand how they are changing, or developing new symptoms or syndromes.
- Educate and increase awareness of these conditions among care providers to facilitate prompt, accurate diagnoses and treatments.
- Educate and increase awareness of these conditions among active duty soldiers and veterans deployed to the Gulf region; work with patient organizations and the National Institutes of Health (NIH) to assist with these efforts.
- Explore opportunities to partner with DOD and NIH to enhance research and improve patient care regarding functional GI disorders.

Relationship between Military Sexual Trauma and Functional GI Disorders

Research in recent decades has studied the relationship between sexual trauma and FGIDs, showing that a history of sexual abuse can directly contribute to the onset of a FGID or place abused individuals at a higher risk for developing a FGID.

Two recent studies concluded that a history of trauma is independently associated with increased risk of developing IBS, the most common FGID. Another study, published last year, showed that military sexual trauma in both male and female veterans is related to an increase in physical illness, primarily pain-related symptoms involving multi-organ systems, including the GI tract.

IFFGD's written statement was submitted to the VA Special Medical Advisory Group as they prepare to make recommendations on the care and treatment of disabled Veterans.

In addition to making the same suggestions as were made to regarding FGIDs and Gulf War Veterans' Illnesses, we also asked that screening for IBS and other FGIDs be implemented for veterans, especially women veterans, who screen positive for military sexual trauma.

DHA Advocacy Day 2014

On June 23rd and 24th, digestive health advocates headed to Washington, D.C. for the seventh annual DHA Advocacy Day. DHA advocates from across the country gathered in the nation's capital for the annual, two-day event to educate Members of Congress about the needs of the functional gastrointestinal and motility disorders (FGIMDs) community.

A networking dinner on Monday 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, National Institute of Diabetes and Digestive and Kidney Diseases, and Lisa Kaeser, J.D., Director, Office of Legislation and Public Policy, Eunice Kennedy Shriver National Institute of Child Health and Human Development, and a review of the 2014 DHA legislative agenda.

On Tuesday, advocates visited Congressional offices to express the importance of research, education, and awareness of FGIMDs. The group, made up of patients, family members of those affected by FGIMDs, and healthcare professionals, all had different stories to share. Some were experienced Capitol Hill visitors who had been with us for Advocacy Day in years past. Others were coming to Washington, D.C. for the first time. All were committed and caring individuals, ready to take action in the hopes of making a difference.

When visiting Congressional offices we discussed the five main points of our 2014 legislative agenda (see page 15). As constituents, it is essential that our Congressional offices be made aware of what is important to us. On our visits we shared special perspectives that can only come from members of the FGIMD community.

During our time in Washington, D.C. we educated 30 offices about FGIMDs and the need for more research to find treatments for these chronic and debilitating conditions. It was an inspiring event that the entire group was happy to experience together.

Digestive Health Congressional Call-In Day 2014

In addition to our efforts in our nation's capital, numerous advocates reached out to their Representatives about The FGIMD Research Enhancement Act on June 17th for the Digestive Health Congressional Call-In Day.

We are thankful to all of our supporters for making sure that the voices of the digestive health community were heard. ■

An Advocate's Story – By Tegan Gaetano

As the most recent addition to the IFFGD staff I had not before experienced a DHA Advocacy Day, nor, for that matter, had I even previously been to Washington, D.C. So, I was in for quite the couple of days.

The city itself looks the part of the head of the nation. Commemorative statues and plaques at every turn, majestic white marble monuments and stately buildings looming over the everyday processes of governance. To an outsider, this looks a lot like chaos, but in reality this is the place where decisions are made that affect our way of life. And, I was excited to be a part of it.

Before I was able to meet with members of the legislative body of the United States, I met the other digestive health advocates. These men and women had gathered together from across the country, some were already close friends introduced at previous Advocacy Days while others were strangers, to make their voices heard. They represented diverse backgrounds, lifestyles, and FGIMD profiles, but were united in their commitment to achieving greater recognition of these prevalent and debilitating, but so often overlooked diseases. The camaraderie we felt in the moment of coming together, knowing that so many others were sending their support even though they could not be there in person, was invigorating. We each recognized this as an opportunity few were afforded – an opportunity to speak to the offices of elected representatives of the people of the United States about a matter that meant a great deal to us.

At our introductory dinner we were briefed on the items on the DHA legislative agenda and leaders from the National Institutes of Health (NIH) and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) discussed topics related to federal funding and research. Next was an impassioned speech by a past advocate. Kat has been living with idiopathic gastroparesis, a condition characterized by certain long-term symptoms along with slow emptying of the stomach, for over six years. There is no known cause of this disorder and no cure. During that time she has had her stomach and large bowel removed. But, through it all she has remained upbeat and cheery, passionate about life and ever hopeful that a cure will be found.

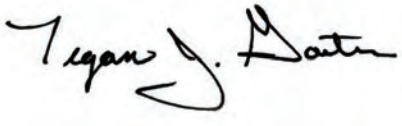
While Kat's retelling of her experiences with gastroparesis was sobering, I was encouraged by the optimism exuded by everyone in the room. Each person had their own story – their own account of how FGIMDs had forever changed their lives. Some had happy endings, like that of Malinda, a gastroparesis-sufferer who was successfully outfitted with a special pacemaker that regulates the contractions of her stomach, and some ended in tragedy, like that of Lonnie, whose wife passed away in 2012 as a result of her gastroparesis. But, each carried with it hope for the future.

The next morning dawned sunny and clear as we made our way to Capitol Hill and split off into groups arranged by state. I accompanied the Pennsylvania group, which included Lonnie and Malinda and her daughter, Zoe, and Arthur, our lone IBS representative. As I walked into my first meeting with a legislative aide of a United States senator, I felt my nerves swell, but I was also charged with the purpose of our message. What's more, I was surrounded by men and women who had faced the very worst and emerged ready to share their stories.

> "Each person who attended the 2014 Advocacy Day... contributed to the betterment of disease outcomes of FGIMDs not only for themselves but for the millions of people living every day with these disorders."

Each legislative aide we met with responded differently to our stories and requests - some listened with quiet politeness while others offered questions and advice. After our final meeting we made our way to our debriefing session to put up our sore feet and meet for the last time as a group. We each shared our impressions of our effectiveness at reaching our audience and applauded each other's efforts. Slowly, the advocates left, giving their goodbyes and hopes for next Advocacy Day.

While I cannot expect that every office we spoke with will immediately take action on our behalf I feel optimistic about the long-range effects of our presence on Capitol Hill. Each person who attended the 2014 Advocacy Day and many more who could be there in spirit only contributed to the betterment of disease outcomes of FGIMDs not only for themselves but for the millions of people living every day with these disorders. To all of them, I say "Thank You."



IFFGD

International Foundation for Functional Gastrointestinal Disorders

This issue of *Digestive Health Matters* is sponsored, in part, by Ferring International PharmaScience Center US, Inc., Forest Laboratories, Inc., Ironwood Pharmaceuticals, Inc., and the supporters of IFFGD. We are grateful for their continued support of IFFGD.

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

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