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In this Issue

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Babies Spitting Up – Normal in Most Cases

Anyone who has ever taken care of an infant knows that babies spit up. And spit up. And then spit up again.

It's easy to understand why some parents and other caretakers are concerned. Is the infant getting enough nourishment? Is frequent spitting up a sign of a more serious illness? Does the baby need medicine to treat the problem?

According to Andrew E. Mulberg, M.D., a pediatrician and pediatric gastroenterologist at the Food and Drug Administration (FDA), frequent spitting up is absolutely normal in most cases and not a symptom of poor health. As long as the child is alert, reasonably content, gaining weight, and not showing other signs of illness, this is not usually a cause for concern, he says.

So what is causing the baby's food to come back up so frequently?

In infants, the ring of muscle between the esophagus and the stomach – the lower esophageal sphincter (LES) – is not fully mature, allowing stomach contents to flow backward, Mulberg explains. In time, the LES will mature and open only when the baby swallows and will remain tightly closed the rest of the time, keeping stomach contents where they belong.

"By the time the child is 18 months of age or younger, the problem – known as gastroesophageal reflux (GER) – usually resolves itself," Mulberg says.

In a small number of cases, a more serious condition known as GERD (gastroesophageal reflux disease) may exist. GERD also can cause excessive spitting up, but requires treatment to avoid additional health complications, such as tissue damage in the lining of the esophagus. A health care professional should be consulted immediately if a baby shows such symptoms as spitting up blood, blood in the stool, weight loss, failure to thrive including lack of weight gain and persistent coughing or wheezing, Mulberg says.

PPIs: Yes or No?

Many parents are worried enough to try over-the-counter (OTC) medications, including proton pump inhibitors (PPIs) such as Prilosec. PPIs work by reducing the amount of stomach acid made by glands in the lining of your stomach and are often used by adults to treat GERD, commonly known as heartburn.

However, PPIs sold over the counter are not approved by FDA to treat reflux in infants, says Mulberg.

An FDA advisory committee met in November 2010 to discuss four clinical trials investigating the effects of PPI treatment of infant GERD. The committee concluded that PPIs should not be prescribed as therapy for otherwise healthy infants less than one year old, Mulberg says, unless there is evidence of tissue erosion in the esophagus.

As for what drugs may or may not be needed, that's a determination the health care professional must make after conducting a thorough physical examination. Mulberg suggests that parents should be ready to discuss the baby's mealtime behaviors in some detail, as well as the child's general mood. Before an appointment, parents should be prepared to answer questions such as:

- Does the baby spit up at every feeding?
- How much liquid is the baby spitting up?
- Are you breast-feeding?
- If not breast-feeding, what type of formula are you using?
- Have you recently switched formulas?

Ways to Cope With Normal Spitting Up

Once a more serious disease is ruled out by the health care professional, there are a number of things parents and other caretakers can do to help prevent babies from constantly spitting up.

These include:

- Holding the baby in an upright position when feeding.
- Feeding the baby smaller portions at a time.
- Thickening feedings with rice cereal or other infant cereals, which help the food to sit in the stomach longer.
- Making a switch to a different formula.

Source: The U.S. Food and Drug Administration's Consumer Updates, *www.fda.gov/ForConsumers/ConsumerUpdates/ucm363693.htm*, (accessed 09.16.2013). This article is not copyrighted.

Clinical Corner

If you or a family member is struggling with chronic or recurring GI symptoms, you probably know how challenging it can be to find reliable treatment information. Clinical Corner provides answers from digestive health professionals to commonly asked questions.

Question:

I have a 10-year-old son who had pancreatitis almost two years ago. He has had so much testing done and a cholecystectomy since then. He has had pain since the pancreatic episode. The pain is unbearable at night. During the day, he seems to keep his mind busy enough that it doesn't hurt as bad... But there are days (and a lot of times after eating) that the pain occurs. It wakes him up.

We've seen a few GI doctors and they claim it is functional abdominal pain and IBS. Are these diagnoses because they can't figure it out? Or does pancreatitis cause functional abdominal pain and IBS?

Answer:

It's complicated. When a person feels well, pain nerves are at rest, said to be sleeping, because they send no pain signals. Any pain experience wakes up sleeping pain nerves and the nerves send pain messages to the brain. In most cases when the cause for the pain is over, the pain nerves go back to sleep.

When pain nerves stay sensitized even after the cause is gone, the result is neuropathic pain, or pain that arises from hypersensitive nerves. Maybe the pancreatitis woke your son's pain nerves, and those pain nerves persist in sending pain messages to the brain even after evidence for disease is gone.

Most GI clinicians are able to find the cause for pain caused by a disease. Your son has had many tests to look for disease, but no disease is apparent at the present time. The absence of easily found disease makes functional or neuropathic pain a probable cause for your son's persistent symptoms. There are no tests for functional, neuropathic pain. The treatment for functional pain is often effective in a matter of weeks.

The first thing to do is regulate sleep so that your son sleeps comfortably through the night and wakes refreshed in the morning. We use a medicine for chronic pain that has sedating properties so that the right dose is the one where sleep is without discomfort or interruption.

The second part to treatment is teaching your son coping skills so that he has ways to help himself reduce the pain sensations. These instructions are taught to your child by a child psychologist using a method called cognitive behavioral therapy or CBT.

There is nothing to lose from a treatment trial for functional pain. If it works, that's great. If it does not work, the next steps for treating pancreatic pain are more invasive.

– Paul E. Hyman, M.D. Director of Gastroenterology Department, Children's Hospital; and Chief, Division of Gastroenterology, LSU Health Sciences Center, New Orleans, LA

A Conversation with a Clinician – Douglas A. Drossman, M.D.

Douglas A. Drossman, M.D. is a long-time supporter of the International Foundation for Functional Gastrointestinal Disorders (IFFGD). As a member of the IFFGD board of directors, as well as chair of the scientific advisory committee, Dr. Drossman has been an important contributor to IFFGD's mission to inform, support, and assist people with functional gastrointestinal (GI) disorders. Dr. Drossman spent 40 years as a professor at the University of North Carolina School of Medicine, where he founded and chaired the world-renowned UNC Center for Functional GI and Motility Disorders. Dr. Drossman is also a founder and president of the Rome Foundation, the organization that sets the criteria for the diagnosis and study of functional GI disorders worldwide.

Q. Dr. Drossman, you have dedicated much of your career to the study and treatment of functional GI disorders. Will you start off by giving us a little history of the field of functional GI?

A. The state of the science of functional GI disorders has evolved throughout my career – when I started in functional GI it didn't exist. The symptoms were understood as disorders of motility, but that wasn't sufficient. We began to see these symptoms as fitting into clusters or patterns and then developed the Rome Criteria. This allows a condition to be reproducibly diagnosed around the world based on the presence (or lack thereof) of specific symptoms. As a result we were able to study larger target populations for epidemiological studies and have a consistent study group for research on pathophysiology and really begin to see how these disorders affect people's quality of life and health.

Organic disease: a disease characterized by a specific structural abnormality, demonstrable on a physical examination, pathology, imaging, or other diagnostic test.

Functional disorder: a disorder or disease where the primary abnormality is an altered physiological function (the way the body works), rather than an identifiable structural or biochemical cause. Altered physiology may occur in terms of motility, sensation, or brain-gut regulation.

There needs to be an understanding that functional GI disorders are real biological entities. These are conditions that are defined *not* by the absence of organic disease, but by the presence of biologic processes – real things that are happening inside the body – that are not visible to the naked eye.

Also, for me, the field of gastroenterology blends together the technical aspects of medicine with the strong focus on the patient. Gastroenterology looks at both a person and his/her symptoms in the context of that person's environment. Daily functioning, quality of life, coping style, and levels of stress all make up that context. A gastroenterologist needs to understand the science in relationship to the biological factors – that is the possible disease and dysfunction of organ systems that produce symptoms – and also how those factors may be modified by the individual's life context.

Q. Much of your work deals with the biopsychosocial model. Will you explain this approach?

A. I was strongly influenced by a great physician and educator, George Engel, M.D. who coined the term "biopsychosocial model." This model integrates the way a patient experiences an illness with its biologic foundation. It is a way for accounting for the interaction between biological, psychological, and social factors. And it applies to all conditions, not just functional GI. There are people with Crohn's Disease or inflammatory bowel disease who totally have no inflammation at all, but they have severe pain. Or, there are people with inflammatory bowel who have severe disease, but have no pain. It is this biopsychosocial understanding of illness and disease that puts the patient's symptoms relative to their disease activity into a clearer and more integrated perspective and opens the door to more effective treatments. This is the type of practice that I choose to do. I find it rewarding to work with someone who has suffered for many years without understanding why and helping them to find the answers and improve their quality of life.

The biopsychosocial model depicts how the gut and brain, genetics and life events, stress and psychosocial distress, all play a role in functional GI disorders. All of these can interact differently from person to person to influence the gut on a cellular level, leading to the observed differences in symptoms, severity, and illness experiences found in individuals with the same conditions.

Q. Your practice, Drossman Gastroenterology, seems to really adopt the concept of patient-centered care. Can you tell us a little bit about that?

A. Patient-centered care is a method of providing care to patients that is respectful and responsive to their preferences and needs, with the patient's values guiding clinical decisions. Actively listening to the patients and collaborating with them on treatments is essential. I truly believe that this principle is a means to increasing personal patient satisfaction, as well as improving clinical outcomes.

Patient satisfaction is extremely important. Data shows that increased patient satisfaction really relates to very simple things. The patient has to see the doctor as humane. The doctor has to have an interest in the patient's medical problem. The doctor has to be seen as technically competent and must also have an interest in their psychological and social environments. The doctor must also work to not give too much biomedical information, as that has a negative response.

There is also evidence that when the doctor and patient work together, improvements in various health outcomes can occur, such as symptom reduction, reduction in blood pressure, in blood glucose, and so on. Physicians can help develop this partner-like relationship by the way they interact with the patient. These skills are not learned through technology or textbooks. Rather it requires that gastroenterologists be mentored from knowledgeable teachers, learn from their own experience with patients, and also possess a genuine desire to help the patient.

This is at the core of what we are trying to do at my practice, and also at the Drossman Center. My vision has been to "translate" the teachings of patient-centered biopsychosocial care to other physicians. It has been a mission of mine to improve health care by creating a Center that teaches communication skills and ways to improve the patient-doctor relationship. And when you reach that level of connection with the patient that is achieved through this concept of patient-centered care, this leads to better clinical results – patients feel better.

Q. What about the patient? What can they do to increase their chances of a better health outcome?

A. Find a doctor who will listen and make sure you're talking to them. The doctor needs to work with you and ask the right questions, but you (the patient) have the right to say when you don't understand something. You should also establish your own set of priorities – but don't overwhelm the communication by stating them all at once. Start with the most important. Also, sometimes patients are most anxious about the thing that is the most important to them or the thing that is the scariest to them, so they don't bring it up initially; rather they wait until they are leaving. By that point many times the doctor doesn't have time. You should begin with the thing that is really concerning you. You want to start with your best move.

It also helps to be self-educated. Reputable sites, like IFFGD.org, drossmangastroenterology.com, or MayoClinic.com, are tremendous educational resources on these disorders. Some of the literature, like that on psychological methods, might seem a little technical and more difficult to understand but it can be helpful. It's a matter of feeling that you can be in control and can speak to your doctor with confidence.

Q. Why is patient education so important?

A. Because functional GI disorders do not have specific findings with laboratory studies, x-ray, or endoscopy, the patients often feel that they don't understand what is going on with their body: that something is being missed or their symptoms are "all in their head." Sometimes patients will go to see a doctor feeling like nobody understands them and nobody can help them. One of two things generally happens at that point. They either feel that a diagnosis has not been made and they take the course of more and more testing, or they feel resigned that no one can help them and they stop trying to look for help and take unneeded treatments, like narcotics. However, knowledge is power; it is important for patients to understand their condition in order to help themselves for a number of reasons. First, the more a patient knows about their condition the more self-assured they will be in speaking with their physician, but there is another reason why it's important. A patient has the capability to down-regulate symptoms. When patients learn about why they are having pain for example, as a result of visceral or central sensitization and the relationship between the brain and the gut, they can accept their symptoms as real and be open to treatment options. By gaining this knowledge they can, in essence, begin treating themselves by reducing anxiety, increasing a sense of understanding and hope, and begin to approach logical and effective treatments, ideally with their doctor.

Q. What do you see as you look to the future of functional GI disorder treatment?

A. I am hopeful. I see that younger doctors are becoming more knowledgeable about patient-centered care, about communication with their patients, and about the newer pathophysiological understanding of functional GI and new treatments. Over the last decade there is an unprecedented amount of knowledge accumulating on brain-gut interactions, GI mucosal immune dysfunction, and alterations in bacterial flora, and this is opening the doors to more novel and effective treatments. In addition, people are starting to think about these disorders from a biopsychosocial context and that will influence how the doctors are treating patients and how patients can increase their role in their own care. I also think it's important for both physicians and their patients, through more education, to truly understand the power of the brain and their ability to modify it.

Dr. Drossman currently sees patients at his practice, Drossman Gastroenterology, in Chapel Hill, North Carolina. His office provides diagnostic treatment services to patients with gastrointestinal disorders that are difficult to diagnose or to manage. In addition to specializing in functional GI, Dr. Drossman has dedicated much of his career to patient-centered care and to helping other physicians better treat their patients by teaching the techniques for effective communication. You can learn more about his practice at the website:

www.drossmangastroenterology.com and his educational approach at *www.drossmancenter.com.* You can also read an article by him on functional abdominal pain syndrome on the following pages.

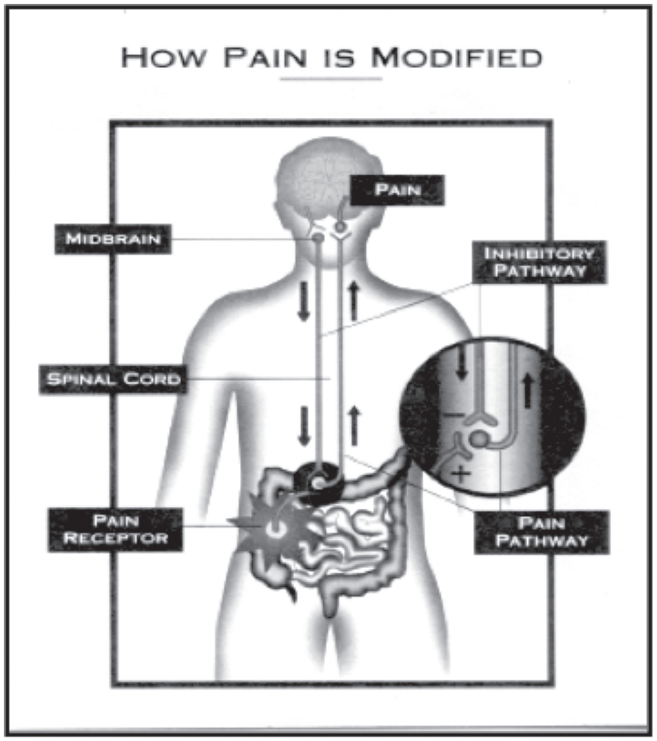
Functional Abdominal Pain Syndrome

By: Douglas A. Drossman, M.D., Adjunct Professor of Medicine and Psychiatry, Co-Director Emeritus UNC Functional GI Disorders Center at University of North Carolina; and Drossman Gastroenterology at Chapel Hill, NC

People with functional gastrointestinal (GI) disorders can have a variety of symptoms that range from painless diarrhea or constipation, to pain associated with diarrhea and/or constipation (usually called irritable bowel syndrome). There is another, less common condition of abdominal pain that is chronic or frequently recurring; it is not associated with changes in bowel pattern. This condition is called functional abdominal pain syndrome (FAPS).

FAPS is a functional GI disorder. There are no abnormal x-rays or laboratory findings to explain the pain. It occurs because of altered sensitivity to nerve impulses in the gut and brain, and it is not associated with altered motility in the intestines.

For people with FAPS, the pain can be so all-consuming that it becomes the main focus of their life. Not only does it impact quality of life, but it has a major economic impact as well. A U.S. Householder Survey of Functional GI Disorders published in 1993, found that people with FAPS missed an average of 12 days of work annually due to illness compared to four missed days for people without GI symptoms. Also, the number of doctor visits in a year averaged 11 for those with FAPS compared with only two for those without FAPS.



Pathophysiology – Understanding Why People Get FAPS

To understand the basis for chronic functional abdominal pain it is helpful to understand how the body experiences pain. Nerve impulses travel from the abdomen to the spinal cord, and then to various areas of the brain. There are many different areas of the brain involved in the sensation of abdominal pain. One of these connected areas is concerned with the location and intensity of the pain, while another connected area is concerned with memories or emotions. Because of this interconnection, the perception of pain can be affected by emotions or life experiences.

While symptoms of FAPS can appear without apparent cause, they can also occur after infections or events that stimulate the bowel and also after traumatic life events like the death of a loved one, a divorce, or a history of sexual or physical abuse. During times of added stress, symptoms can worsen.

Repeated injury in the abdomen can cause nerve receptors to become overly sensitive. For instance, if someone has had multiple abdominal surgeries or an infection, a later painful occurrence may be experienced as more painful than previously. Even normal abdominal activity may be experienced as being painful. It is as if the volume has been turned up on a stereo receiver. This condition is called visceral hypersensitivity (i.e., increased sensitivity of the intestines). Furthermore although the brain has an ability to "turn down" the pain signals from the GI tract with FAPS, this ability is reduced, so even small amounts of intestinal disturbance can be amplified to produce severe pain (central hypersensitivity). So these individuals have an altered "brain-gut axis" where there is a failure of the brain to regulate even normal gut nerve activity leading to increased pain.

Understanding how the brain can modify the pain experience (for better or worse) is essential to beginning any treatment. When someone is feeling anxious or depressed, or focuses attention on the pain, it is experienced as more severe. The use of relaxation training or other techniques can divert attention away from the pain.

If a person has previously had a bad encounter with pain, the fear of having the pain again can actually make the pain worse the next time. If a person takes steps to feel in control of the pain, symptoms will improve. In addition, the amount of support a person receives from family, friends, and other sources can affect how a person responds to pain.

Treatment Strategies

Given what we currently know about FAPS, the aim of treatment is to help you gain control over your symptoms and improve daily function, rather than totally eliminate symptoms, which usually is not possible. One way to start is to keep a diary to record symptom flare-ups, and to identify possible triggers (emotional and situational). This kind of information may be used by you or your physician to help develop better strategies to control the symptoms. [Contact IFFGD for a Personal Daily Diary for people with functional GI disorders.]

The brain not only affects how you sense pain, it is also able to block pain. Think about the basketball player who sprains his ankle during a game and continues to play without awareness of pain. Then, when the game ends, he collapses to the floor, unable to walk. He was able to block the pain by focusing his attention on the game.

When nerve impulses travel up from the abdomen to the spinal cord, some of them go through a kind of "gate" that is controlled by nerve impulses coming down from the brain. These impulses from the brain can block or inhibit pain signals going from the abdomen to the brain by "closing" the gate. Alternatively, they can increase signals to the brain by opening the gate.

Because the brain has such a strong influence on the sensation of pain, psychological treatments can relieve symptoms of FAPS by sending signals that close the gate. Different techniques include relaxation, imagery, hypnosis, and cognitive-behavioral therapy. (Table 1)

Table 1 – TREATMENT OF FAPS:

THE MIND-BODY CONNECTION

- Symptom diaries – Helps you see what events or emotions make symptoms worse.
- Stress management (i.e., relaxation techniques, meditation) – Teaches you how to focus attention on something other than the pain.
- Hypnosis – Helps you focus attention away from the pain. Positive suggestion can change ways you think or react.
- Cognitive-behavioral therapy – Teaches you how to change non-helpful thoughts, perceptions, and behaviors to control symptoms.

Medications may also be used in the treatment of FAPS. For continuous or severe abdominal pain, your doctor might prescribe an antidepressant. It is important to understand that these medications are not just used to treat individuals who have depression but also act as pain relievers (central analgesics) for treatment of FAPS and many other painful conditions.

Antidepressant medications can help stimulate the brain to increase the signals, which block pain transmission from the abdomen to the brain. It may take several weeks before a difference is noticed. (Table 2)

Table 2 – TREATMENT OF FAPS:

MEDICATIONS

- Antidepressants act as pain relievers.
- These medications stimulate the brain to send signals and close the pain-control gate in the abdomen.
- Antidepressants might take several weeks to work, so you shouldn't stop taking them until your doctor tells you to do so.
- Side effects are possible but usually go away after a few days.

Some people will experience side effects from antidepressant medications. Usually, the side effects will go away after a few days so it is important to stay with the medication until treatment benefit is obtained. The tricyclic antidepressants (TCAs) can cause dry mouth and drowsiness. Another group of antidepressants is called selective serotonin norepinephrine reuptake inhibitors (SNRIs). These can cause side effects like nausea. Both of these classes of antidepressants are helpful for treating pain. Finally, it is becoming increasingly common to use combinations of treatments like a medication for the bowel and an antidepressant or two types of medications to affect the brain's pain control or a behavioral treatment like cognitive behavioral treatment with an antidepressant. These combinations can improve the pain benefit while keeping side effects at a minimum.

It is important to realize that narcotics are *not* indicated – and can even be harmful and need to be avoided – in treating chronic abdominal pain. Over long periods of time, narcotics may produce more pain causing a condition called "Narcotic Bowel Syndrome."

The Patient-Doctor Partnership

It is important that you work with a physician who demonstrates empathy toward you and an understanding of the symptoms of FAPS. It is a disorder where treatment requires the participation of both you and your physician.

Treatments for FAPS are most effective when the patient and the doctor work as a team, each having a role. Your doctor has the responsibility to educate you about FAPS. He or she should answer your questions and provide you with an understanding of what your symptoms are about and what your treatment options are.

You need to express your views about your treatment goals, work with your doctor to develop the treatment plan, and work toward putting the plan into action. If you follow the treatment plan closely, you and your doctor will be better able to track your results. This will allow you to achieve the best possible relief of abdominal pain.

Clinical Trials Pave the Way for New Treatments

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

What is a Clinical Trial or Study?

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

What is a Protocol or Study Plan?

A protocol is a study plan carefully designed to safeguard the health of the participants as well as answer specific research questions. A protocol describes what types of people may participate in the trial; the schedule of tests, procedures, medications, and dosages; and the length of the study. While in a clinical trial, participants following a protocol are seen regularly by the research staff to monitor their health and to determine the safety and effectiveness of their treatment.

While efforts are made to control risks to clinical trial participants, some risk may be unavoidable because of the uncertainty inherent in clinical research involving new medical products. It's important, therefore, that decisions to participate in a clinical trial are made only after obtaining a full understanding of the entire process and the risks that may be involved.

Where Can I Find out More?

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

After identifying a trial of interest to you, the next step is to contact the study research staff and ask questions about specific trials.

Here is a list of several studies which are currently seeking participants.

NIH Gastroparesis Clinical Research Consortium

Purpose: The Gastroparesis Clinical Research Consortium is recruiting patients for their gastroparesis registry. Those who sign up for the registry may be contacted about participating in trials or surveys about gastroparesis to advance the science of the disorder to better understand and treat gastroparesis.

Sponsored by: National Institutes of Health (NIH), Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

Contact: James Tonasci, Ph.D., 410-955-3704; *jtonasci@jhsph.edu;* Aynur Unalp-Arida, M.D., 410-614-4851, *aunalp@jhsph.edu*

Study of Genetic and Environmental Factors that Cause/Influence IBS

Purpose: This study involves measuring the relationship between genes, the environment, and various psychological and health factors in men and women with IBS. Individuals who participate will spend one overnight visit in the General Clinical Research Center at UNC Hospital. No additional visits required.

Study Location: University of North Carolina Center for Functional GI and Motility Disorders, Chapel Hill, North Carolina; Principal Investigator: William E. Whitehead, Ph.D.

Participation: Eligible male and female participants aged 18 and older for patient group and healthy control group

Compensation: $250-$300 for participants completing the study. Healthy control subjects without symptoms of IBS will receive $50.

Contact: Lenore Keck, 919-966-8329, *akeck@med.unc.edu*

Two Trials of Elobixibat for Use in Patients with Chronic Idiopathic Constipation

Purpose of study 1: This is a 26-week, Phase 3, Efficacy and Safety Trial for Patients with Chronic Idiopathic Constipation

Purpose of study 2: This is a 12-week, Phase 3, Efficacy and Safety Trial Followed by a 4 Week Withdrawal Period for Patients with Chronic Idiopathic Constipation

Sponsored by: Ferring Pharmaceuticals

Participation: Eligible male and female patients aged 18 years and older

Contacts: Clinical Development Support, *DK0-Disclosure@ferring.com;* Be sure to refer to these studies with their ClinicalTrial.gov identifiers: NCT01827592 (study 1) and NCT01833065 (study 2)

What are Phases?

Treatment trials or studies are in phases:

Phase 1 tests a new drug or treatment in a small group to evaluate its safety, determine a safe dosage range, and identify side effects.

Phase 2 expands the study to a larger group to see if it is effective and to further evaluate its safety.

Phase 3 expands the study to an even larger group of people to confirm its effectiveness, monitor side effects, and collect information that will allow the drug or treatment to be used safely.

Trial to Investigate Dexlansoprazole for the Treatment of Larygopharyngeal (Throat Related) Reflux

Purpose: This is a double-blind, placebo-controlled trial to investigate dexlansoprazole (Dexilant), a twice-daily release proton pump inhibitor requiring once daily dosing, for the treatment of larygopharyngeal reflux.

Sponsored by: Indiana University

Participation: Eligible male and female patients aged 18 years or older

Contact: Stacey L. Halum; 317-688-4824; *shalum@iupui.edu* or Heather Hillman; 317-688-4864; *hhillman@iuhealth.org;* Be sure to refer to this study by its ClinicalTrials.gov identifier: NCT01317472

Study of Methylnaltrexone (Relistor) to Treat Opioid-Induced Constipation

Purpose: This is a three-month, open label study that will evaluate the safety of methylnaltrexone (Relistor) in advanced illness patients who have constipation caused by opioid pain relievers. This is an extension of a previous study.

Sponsored by: Salix Pharmaceuticals

Participation: Eligible male and female patients aged 18 and older

Contact: Dave Matthews; 919-862-1000; *dave.matthews@salix.com;* Be sure to refer to this study by its ClinicalTrials.gov identifier: NCT00672139

Study of Recurrent Abdominal Pain in Kids

Purpose: This study looks at ways to help children with recurring stomachaches that have no known cause. No medicines are used for this study. Children and parents will make three, hour-long visits to a counselor or social worker to learn ways to deal with stomachaches.

Study Location: Children's Hospital Division of Gastroenterology (Seattle) and the University of Washington Children's Hospital (Seattle) and the University of Washington

Participation: Eligible children aged 8 to 16 years and their parents

Compensation: $150 total by the end of the study

Contact: Recurrent Abdominal Pain Study, 206-616-2358

Two Phase 2 Studies of Dexlansoprazole for use in Adolescents

Purpose of study 1: This is a 36-week study to assess the safety and effectiveness of dexlansoprazole (Dexilant) delayed-release capsules for healing of erosive esophagitis and maintenance of healed erosive esophagitis and relief of heartburn in adolescent subjects.

Sponsored by: Takeda Pharmaceuticals

Participation: Eligible male and female patients aged 12 to 17 years

Contact: Takeda Study Registration Call Center; 1-800-778-2860; *medicalinformation@tpna.com;* Be sure to refer to this study by its ClinicalTrials.gov identifier: NCT01642615

Purpose of study 2: This is a 4-week study to assess the safety and effectiveness of dexlansoprazole (Dexilant) delayed-release capsules for relief of heartburn in adolescent subjects with symptomatic non-erosive gastroesophageal reflux disease.

Sponsored by: Takeda Pharmaceuticals

Participation: Eligible male and female patients aged 12 to 17 years

Contact: Takeda Study Registration Call Center; 1-800-778-2860; *medicalinformation@tpna.com;* Be sure to refer to this study by its ClinicalTrials.gov identifier: NCT01642602

Study of Rifaximin to Treat Irritable Bowel Syndrome with Diarrhea (IBS-D)

Purpose: This study will evaluate the effectiveness and safety of repeat treatment with rifaximin 550 mg three times a day in patients with IBS with diarrhea who respond to initial treatment of rifaximin 550 mg three times a day.

Sponsored by: Salix Pharmaceuticals, Inc.

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

Contacts: Rachel Ballard; *rachel.ballard@salix.com* or Alyson Lineberry; *alyson.lineberry@salix.com;* Be sure to refer to this study by its ClinicalTrials.gov identifier: NCT01543178

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

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

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

IFFGD INDUSTRY COUNCIL

Sucampo Pharmaceuticals, Inc.
and Takeda Pharmaceuticals USA, Inc.

Salix Pharmaceuticals, Ltd.

NPS Pharmaceuticals, Inc.

Ironwood Pharmaceuticals, Inc.

Forest Laboratories, Inc.

Ferring International Pharmascience Center US, Inc.

Treatment News

FDA Advisory Committee on Relistor

On June 11, 2013 Salix announced that the U.S. Food and Drug Administration (FDA) will be holding an advisory committee to review Salix's Supplemental New Drug Application, which seeks to extend the use of Relistor to include patients who are taking opioids to treat chronic pain.

Relistor was approved in the United States in 2008 for short term treatment of opioid-induced constipation in patients with advanced illness who are receiving palliative care when response to laxative therapy has not been sufficient. It has also received approval for this indication in other countries.

Elobixibat Now in Phase 3 Clinical Trials

Ferring Pharmaceuticals announced in May 2013 that it has entered Phase 3 trials of elobixibat for the indication of chronic idiopathic constipation (CIC). Two studies are being conducted at close to 200 sites around the world.

Elobixibat is a first-in-class compound under investigation for treatment of CIC and for IBS with constipation (IBS-C). It works by reducing bile acid absorption in the small intestine. This stimulates bowel movements by increasing fluid secretions and motility in the colon.

In Phase 2b clinical trials, elobixibat (formerly A3309) has been evaluated in patients in the U.S. and Europe for the treatment of CIC. The studies demonstrated clinically meaningful, statistically significant, and dose-dependent improvements. These included increased stool frequency and improved constipation-related symptoms such as straining, stool consistency, and bloating maintained over eight weeks of treatment.

Participants Sought for Two Double-blind, Randomized, Placebo-controlled, Phase 3 Trials in Patients with Chronic Idiopathic Constipation to Demonstrate the Efficacy and Safety of Elobixibat 5 mg and 10 mg

Purpose of study 1: 26-week Efficacy and Safety Trial for Patients with Chronic Idiopathic Constipation
Sponsored by: Ferring Pharmaceuticals
Participation: Eligible male and female patients aged 18 years or older
Contact: Clinical Development Support; *DK0-Disclosure@ferring.com*

Purpose of study 2: 12-week Efficacy and Safety Trial Followed by a 4-week Withdrawal Period for Patients with Chronic Idiopathic Constipation
Sponsored by: Ferring Pharmaceuticals
Participation: Eligible male and female patients aged 18 years or older
Contact: Clinical Development Support; *DK0-Disclosure@ferring.com*

Linaclotide now Available in Europe for Treatment of IBS-C

On June 12, 2013 Ironwood Pharmaceuticals and Forest Laboratories announced that linaclotide is available in some countries in Europe (Germany, the UK, and Nordic countries) to treat IBS with constipation (IBS-C). It will become available in more European countries during 2013 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. Linaclotide 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.

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

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 (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 has not yet been approved by the U.S. Food and Drug Administration (FDA) for the treatment of IBS.

Seeking Participants for Study to Assess Repeat Treatment Efficacy and Safety of Rifaximin 550 mg TID in Subjects with Irritable Bowel Syndrome with Diarrhea (IBS-D)

Purpose of study: This study will evaluate the effectiveness and safety to repeat treatment with rifaxamin 550 mg three times a day in patients with IBS with diarrhea who respond to initial treatment of rifaxamin 550 mg three times a day.

Sponsored by: Salix Pharmaceuticals, Inc.

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

Contacts: Rachel Ballard; *rachel.ballard@salix.com* or Alyson Lineberry; *alyson.lineberry@salix.com* Be sure to refer to this study by its ClinicalTrials.gov identifier: NCT01543178

Lubiprostone is Approved by the FDA to Treat Opioid-Induced Constipation

In April 2013 Sucampo Pharmaceuticals, Inc. and Takeda Pharmaceuticals U.S.A. Inc. announced that the U.S. Food and Drug Administration (FDA) approved the supplemental New Drug Application for lubiprostone (Amitiza) 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 stomach 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.

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

Teduglutide Studied to Treat Short Bowel Syndrome

An international, multi-center study of teduglutide (Gattex) took place in January 2013, looking at the safety, tolerability, and efficacy of the drug taken once per day over 52 weeks for the treatment of people with short bowel syndrome (SBS) receiving parenteral nutrition (PN). The study concluded that, for patients with SBS and intestinal failure, the efficacy of teduglutide was maintained over 52 weeks and the safety profile was sufficient to be considered for long-term use.

Gattex is a product of NPS Pharmaceuticals, a specialty pharmaceutical company developing orphan therapeutics for rare gastrointestinal and endocrine disorders. It is a novel peptide involved in gastrointestinal regeneration and repair (recombinant analog of human glucagon-like peptide 2). Gattex works by regeneration of cells in the intestinal lining, slowing down transit through the gut and increasing blood flow, allowing for increased nutrient absorption. In studies, the drug was associated with achieving and maintaining clinically meaningful reductions in PN and IV fluid volume in adult subjects with SBS.

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 and cannot absorb enough water, vitamins, and other nutrients from food. They may then need to use PN and intravenous (IV) fluids, the slow infusion of a solution of nutrients and fluids into a vein.

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.

Teduglutide (Gattex) was approved by the U.S. Food and Drug Administration (FDA) in 2012 for treatment of adult patients with SBS who are receiving PN 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.

The European Commission granted European market authorization in August 2012 for the medicinal product teduglutide (trade name in Europe: Revestive) as a once-daily treatment for patients with SBS. In March 2013, NPS reacquired the rights to teduglutide outside of the U.S., Canada, Mexico, and Israel from Takeda GmbH.

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

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

Fecal incontinence is the involuntary loss of bowel control. While the exact mechanism of action has not been identified, it is thought that the Solesta injections may narrow the anal canal and allow for better control of those muscles.

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 experienced in performing anorectal procedures who 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.

Be an Active Member of your Health Care Team

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

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

- **S**peak up – the more information your health care team knows about you, the better the team can plan the care that's right for you.
- **A**sk questions – write down a list of all of your questions and take notes on the answers. If you don't understand an answer, be sure to ask your question again.
- **F**ind the facts – learn as much as you can about your prescription or over-the-counter (OTC) medication. Find out things like brand and generic names, possible interactions, side effects, and directions for you usage. And remember to ask questions if you need more information.
- **E**valuate your choices – weigh the benefits and risks of your choices after you have all of the information to help you make the right decision for you.
- **R**ead the label and follow directions – before you leave the pharmacy with your medication, make sure you have the right medicine, know the right dose to use, and know how to use it. When you're ready to use the medicine, make the most of the benefits and lower the risks by following the directions.

Source: *http://www.fda.gov/Drugs/ResourcesForYou/ucm079453.htm* (accessed 09.16.2013)

Medical and Research News

NIH Holds Workshop on Clinical Research Agenda for Fecal Incontinence

The National Institutes of Health (NIH)) held a workshop August 19–20, 2013 to answer questions about research in fecal incontinence. Despite its serious effects on patients, families, and society, fecal incontinence is often ignored and has been studied less than many other conditions. It has been difficult to identify persons at risk for, or affected by, fecal incontinence because the condition is often not reported or diagnosed. Prevention of fecal incontinence has been hindered by limited research and incomplete knowledge about the biological causes and interacting social and environmental factors.

The workshop included a panel of experts in epidemiology, gastrointestinal physiology, gastroenterology, colorectal surgery, urogynecology, psychology, and behavioral medicine. During the workshop, they identified and discussed major issues in the diagnoses and treatment of fecal incontinence. In addition, the panel examined the barriers encountered in addressing fecal incontinence. Furthermore, the panel was charged to develop research priorities in both basic and clinical research to further advance treatment strategies for fecal incontinence.

New Guidelines for the Diagnosis and Treatment of Achalasia

On July 23, 2013 the American College of Gastroenterology published new guidelines for the diagnosis and treatment of achalasia. Achalasia is a motility disorder in which the esophagus (food tube) empties slowly. The new guidelines for proper diagnosis include several test methods as appropriate when achalasia is suspected. Manometric tests, which show irregular muscle contractions (peristalsis) and incomplete opening of the lower esophageal sphincter, will help confirm the diagnosis so that patients can receive correct treatment tailored to their preferences and the expertise of their care provider.

Eluxadoline Shows Promise in IBS-D

Results published in the medical journal *Gastroenterology* of a phase 2 clinical trial of a new treatment for IBS-D has shown promising results. The treatment, eluxadoline, is a mu opioid receptor agonist and delta opioid receptor antagonist. The results indicated that eluxadoline helped both decrease abdominal pain and improve stool consistency, as well as improving study subjects' self-reported quality of life. Phase 3 trials are concluding and results from those trials should be published sometime in the future.

FDA Defines "Gluten-Free" for Food Labeling

On August 2, 2013 the U.S. Food and Drug Administration (FDA) published a new regulation defining the term "gluten-free" for voluntary food labeling. The definition standardizes the meaning of "gluten-free" claims across the food industry including a requirement that the food must contain less than 20 parts per million of gluten. Foods with the claims "no gluten," "free of gluten," and "without gluten" must meet the definition for "gluten-free." While many foods currently labeled as "gluten-free" may be able to meet the new federal definition already, food manufacturers will have a year to bring their labels into compliance with the new requirements.

Study Looks at Liquid and Fiber Intake in Constipation

Researchers at the University of North Carolina at Chapel Hill published a review study looking at the association between a low-fiber diet and liquid intake in adults with constipation. Researchers reviewed data on over 10,000 adults collected by surveys between 2005 and 2008. They reviewed dietary data on these subjects and found that low liquid intake increased the odds of having constipation. The researchers conclude that this may support treating constipation by increasing fluids but note that their study had some methodological limitations, and more evidence is needed.

Alphabet Soup

Sometimes the agencies, programs, and offices involved in our legislative activities can look like a string of letters in a bowl of alphabet soup. Here are some of the acronyms we use in this issue of *Digestive Health Matters.*

CDMRP – *Congressionally Directed Medical Research Program*

This is a medical research program funded every year by Congress as part of the Defense Appropriations Act with disease-specific focus. Applications and programs are reviewed by scientists, clinicians, and consumers.

DOD – *Department of Defense*

It is America's oldest and largest government agency, in charge of providing the military forces needed to deter war and to protect the security of our country. Employees include both military and non-military members.

FY – *Fiscal Year*

This is a period of calculating annual financial statements. It is not always the same as a calendar year. Businesses can set their own fiscal year. The federal government's fiscal year runs from October 1st through September 30th.

GWIRP – *Gulf War Illness Research Program*

This is a medical research program funded every year by Congress through the DOD as part of the Defense Appropriations Act. Projects focus on studying the health effects of service members deployed to the Gulf War region, including functional GI disorders.

HHS – *U.S. Department of Health and Human Services*

This government agency is responsible for protecting the health of all Americans and providing essential human services. It includes the Office of the Secretary and 11 operating divisions, such as the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the NIH.

NIDDK – *National Institute of Diabetes and Digestive and Kidney Diseases*

This is the branch of the NIH responsible for conducting and supporting medical and scientific research focused on diabetes and other endocrine and metabolic diseases; digestive diseases, nutritional disorders, and obesity; and kidney, urologic, and hematologic diseases.

NIH – *National Institutes of Health*

This is the nation's medical research agency and the largest source of funding for medical research in the world. It is made up of 27 Institutes and Centers, each focused on a specific research topic, such as NIDDK, the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), or the National Cancer Institute (NCI).

PRMRP – *Peer-Reviewed Medical Research Program*

This program was established in FY 1999 as part of the DOD to support research in science and medicine to enhance the health and well-being of military personnel, their families, and veterans. It is funded through Congressional appropriations.

Sharing Stories, Taking Action for H.R. 842

Since the 113th Congress began in January, over 3,000 bills have been introduced in the U.S. House of Representatives. So it takes a lot to make any one piece of legislation stand out from the crowd. For three Members of Congress, digestive health advocates have managed to do just that for *The Functional Gastrointestinal & Motility Disorders (FGIMD) Research Enhancement Act of 2013* (H.R 842).

Digestive health advocate Crystal poses outside of Rep. Slaughter's office during the 2013 DHA Advocacy Day.

In July, Representatives Louise McIntosh Slaughter (NY-25), Bill Posey (FL-8), and Ed Perlmutter (CO-7) all became cosponsors of *The FGIMD Research Enhancement Act.* These Representatives added their names to H.R. 842 because constituents shared with them the impact of functional GI and motility disorders on their lives and made the need for the research and treatment provisions of *The FGIMD Research Enhancement Act* stand out.

In order to pass the House of Representatives, H.R. 842 will need the support of 218 Representatives. With the addition of Representatives Slaughter, Posey, and Perlmutter, there are currently 13 supporters in the House of Representatives, with 205 left to go! Make sure that your Representative knows how important this bill is by sharing your story with them at *www.IFFGD.org/HR842action.*

The cosponsors of H.R. 842 are listed below.

- Julia Brownley (CA-26)
- Gerald E. Connolly (VA-11)
- Susan A. Davis (CA-53)
- Ron Kind (WI-3)
- James McGovern (MA-2)
- Gwen Moore (WI-4)
- James P. Moran (VA-8)
- Ed Perlmutter (CO-7)
- Bill Posey (FL-8)
- Bobby L. Rush (IL-1)
- F. James Sensenbrenner (WI-5)
- Louise McIntosh Slaughter (NY-25)
- Peter Welch (VT)

Rep. Perlmutter meets with digestive health advocate Natalie and her son Grant

2014 Defense Spending: What it Means for Functional GI Research

As part of our advocacy initiatives, the Digestive Health Alliance (DHA) supports funding for the Gulf War Illness Research Program (GWIRP) through the Department of Defense (DOD) Peer-Reviewed Medical Research Program (PRMRP). Functional gastrointestinal (GI) disorders have been included in GWIRP since fiscal year (FY) 2012. This came about after a 2010 Institute of Medicine report recognized a presumptive service connection between the development of these chronic digestive disorders and deployment in the Gulf War region.

Research into functional GI disorders and veterans affects not only those who have served, but all people suffering with functional GI disorders. As the Senate committee stated in the report accompanying the DOD Appropriations bill, "medical research being conducted by the Department that yields medical breakthroughs for service members and often translates to the civilian population, as well."

As the budget for FY 2014 is discussed in both the House of Representative and the Senate, discussions on funding for the DOD will affect the PRMRP. In August, both chambers of Congress discussed the level of funding for the DOD.

The House of Representatives passed its version of the DOD Appropriations bill which included an amendment added by Representative Al Grayson (FL-9) that provides an additional $10 million to "specifically target finding a cure for Gulf War Illnesses." This would bring the total funding for the GWIRP to $30 million, up from $20 million in FY 2013.

In the Senate, the DOD Appropriations bill has not yet been voted on, but it has been discussed in the Appropriations Committee. Remarks from Committee members repeatedly praised the DOD Appropriations bill for its significant investment in medical research activities. The final Committee Report includes $200 million for the PRMRP, which is an increase of $150 million over the last fiscal year. Included on the list of items of interest eligible for study by the PRMRP is Gulf War Illness. The bill will now move to the full Senate for consideration.

If and when the Senate bill is passed, a conference committee with members from both the House and the Senate will likely need to meet to discuss the differences between the two versions of the FY 2014 DOD Appropriations bill and to come to an agreement. Like all bills, it will need to pass both houses of Congress with the exact same language in order to become law. DHA will support Representative Grayson's amendment for increased funding for GWIRP during this process and will keep you posted as this unfolds.

Senate Committee Discusses NIH Funding for 2014

The Senate Appropriations Committee has considered and passed its bill concerning funding for the Departments of Labor, Health and Human Services, Education, and Related Agencies (L-HHS) in fiscal year (FY) 2014. Known as the Senate L-HHS Appropriations bill, its $165 billion decides how much funding government programs such as the Centers for Disease Control and Prevention, Department of Education, and Social Security would receive in 2014.

Perhaps the most exciting thing about the Senate L-HHS Appropriations bill is that the report accompanying the bill addresses functional gastrointestinal (GI) disorders directly! On page 89 of the report submitted by Senator Tom Harkin (IA) it states, "The Committee continues to urge the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) to engage in multi-Institute collaborations to improve understanding of functional GI disorders." This sentiment is also a part of *The Functional GI & Motility Disorders Research Enhancement Act* (H.R. 842). The Digestive Health Alliance (DHA) appreciates the continued support in the Senate for these disorders.

The Senate L-HHS Appropriations bill would fund the National Institutes of Health (NIH) at a level of $30.955 billion next year, as was recommended by the Senate Appropriations Subcommittee on L-HHS. Although $30.955 billion for NIH in FY 2014 would be an increase of about $1.8 billion over last year's post-sequestration funding level, it does not reach the $32 billion supported by DHA and the broader health community.

Included in the proposed funding for NIH is $1.799 billion for NIDDK. This is an increase of $6.295 million over the FY 2013 enacted level. Of the 27 NIH Institutes and Centers, NIDDK is where the majority of federally supported functional GI and motility disorder research is conducted.

It is uncertain what the next steps are for the Senate L-HHS Appropriations bill. Senate leadership will decide whether to bring the bill up for consideration by the full Senate or to use the committee-passed bill in anticipated negotiations with the House of Representatives.

Although the House has not yet considered its L-HHS Appropriations bill, the funding reserved for L-HHS in their total proposed FY 2014 federal budget is only $122 billion. This proposed level of funding is 26% lower than the Senate's proposed $165 billion. The House is not expected to finalize their version of the L-HHS Appropriations bill, but even if they do it will be majorly different from the Senate L-HHS.

Since any bill must pass both the Senate and the House of Representatives with the same language, the differences that will exist between any House version and Senate version of the L-HHS Appropriations bill will help set up the usual annual struggle to finalize this appropriations legislation. As a result, instead of a complete budget for FY 2014, there is likely to be at least a short-term continuing resolution to start the fiscal year on October 1, 2013.

DIGESTIVE HEALTH ALLIANCE

Community of Digestive Health Champions at DHA.org

IFFGD has created an easy way for everyone to become part of the digestive health community. Our new web platform at DHA.org gives those affected by functional GI and motility disorders the chance to become digestive health champions. People can raise much needed awareness and funds for research of chronic digestive conditions, share personal stories, and educate policy makers and others through advocacy.

"There are millions of people living with the effects of functional GI and motility disorders, whether they themselves are experiencing symptoms or their friends or family members are afflicted with the disorders," said Nancy Norton, president and founder of IFFGD. "We created DHA.org, a place where the community can come together to find strength and support and to create meaningful change, in the hopes of improving treatment options and finding cures for these conditions."

DHA.org also offers online discussion forums where individuals can interact and support one another, illustrating the point that they are not alone in their experiences. Some current discussion topics are:

- Has anyone tried a low FODMAP diet for IBS?
- Does anyone have trouble sleeping because of reflux or heartburn? What helps you get a good night's rest?
- What makes you feel better when you're feeling bad? For me, it's Seinfeld re-runs!
- What gastroparesis-friendly foods have you discovered? Please share any recipes.

Here is an example of a current community discussion about Hirschsprung's disease, a congenital disorder where children are born missing the nerve cells within the wall of their colon or rectum.

Topic: SURGERY FOR HIRSCHSPRUNG'S DISEASE

March 13, 2013 - Anonymous
Does anyone have a child who has undergone surgery for Hirschsprung's disease? Surgical treatment for HD is standard, but we want to know how your family coped with the surgery. What was the experience like?

April 23, 2013 — Canadian
My son underwent this surgery at 2 months. He is now 11. The surgical procedure went well. Over the years we have monitored for bowel bleeding constipation and bloating. We have been successful as far as the surgery and he suffered minimal scars.

May 23, 2013 — SteffanyNB13
I was born with Hirschsprung's disease (I am a 28 year old female) and had a pull through done when I was an infant (7 inches removed of colon). I've been fine ever since. I have two boys, my oldest was fine when he was born but my youngest at 4 years old has had a lot of problems. He was born and diagnosed with Hirschsprung's disease at 4 days old, had 80% of his colon removed at 9 days old. He did fine for a while until he was about 1.5-2 years old, then he started having severe enterocolitis (inflammation of the intestines). We had biopsies done and he was missing the ganglion cells in the remainder of his large intestine. They did an ileostomy (a surgically created opening in the abdomen that allows the diversion of waste material) and he had a bag for about 6 months, they reversed it and took out the remainder of his large intestine. It was a HUGE decision for us and I was terrified of what the future was going to hold. That was about 2 years ago and ever since his surgery, he has had perfect weight gain and is just like any other little 4 year old. The only thing we watch now is that he stays hydrated (that is our number one issue--living in Florida especially) and emptying himself properly. But it is night/day difference than what is was before. He had to be dilated multiple times a day, was given laxatives and antibiotics, and he had HORRIBLE diaper rashes that required the most expensive creams. No issues whatsoever now. If the biopsies come back that there are no ganglion cells, the only treatment is surgery (unfortunately) and depending on the type of procedure (Swenson, Soave, Duhamel, and Boley procedures) the outcome can create a completely different child! His first initial surgery (the 80% removed) was at Tripler Hospital in Hawaii where he was Emergency transferred to from Okinawa, Japan. His second surgery was at Shands at University of Florida and that is where he continues to be seen. I absolutely LOVE his doctor. There are a lot of other parents I have met whose children were born with Hirschsprung's disease.

June 11, 2013 — Dea0623
My son is 3 years old and underwent surgery for Hirschsprung's disease at 1 week old. I can relate with your history. Horrible rashes and incontinence is part of my daily routine, always trying to make him feel better. It is very stressful. I would love to know the name of your doctor in Florida. We are relocating to Ft Myers and I need to find a good doctor that has knowledge about Hirschsprung's. Thank you!

This issue of *Digestive Health Matters* is sponsored, in part, by Salix Pharmaceuticals, Inc., and the members 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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