

## A BILL

To amend the Public Health Service Act to provide for the expansion, intensification, and coordination of the activities of the National Institute of Diabetes and Digestive and Kidney Diseases with respect to research on irritable bowel syndrome (IBS) and the functional GI disorders (FGIDs).

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

### SECTION 1. SHORT TITLE.

This Act may be cited as the 'IBS and Functional GI Disorders Research and Treatment Act of 2010'.

### SEC. 2. FINDINGS.

The Congress finds as follows:

(1) Irritable bowel syndrome (IBS) is one of a spectrum of conditions known as functional gastrointestinal disorders (FGIDs), which include functional dyspepsia, nausea and vomiting disorders, fecal incontinence and others, that impair gastrointestinal functioning. These disorders involve disturbances of intestinal motility, sensation and secretion. They can produce symptoms of pain, bloating, nausea, diarrhea, and constipation.

(2) IBS and the FGIDs can severely compromise a person's quality of life. It is estimated that 15% of the population has some activity limitation and impairment of daily function, due to IBS and a larger proportion have similar impairment with other FGIDs. It is speculated that the actual prevalence may be even higher given that those affected often do not seek treatment due to the perceived stigma and personal humiliation associated with the symptoms of the disorder, such as incontinence.

(3) For IBS alone health care costs to society are \$2 billion annually and exceed \$19 billion when factors such as loss of work and productivity are considered. Furthermore the FGIDs are the most common gastrointestinal conditions seen in primary care practice and are over 40% of gastrointestinal problems seen by gastroenterologists. IBS alone is second only to the common cold for causing absenteeism from work.

(4) IBS and the FGIDs are characterized by unusually sensitive nerve endings in the bowel wall as well as dysfunction of brain-gut regulatory pathways. Their causes are not fully understood but environmental factors, such as stress, and more specifically post-traumatic stress disorder are known to be catalysts for the onset of symptoms.

(5) While it would be beneficial to identify the underlying causes of IBS and FGIDs, there is current evidence that pharmacological and

behavioral treatments reduce symptoms and improve quality of life for them. Moreover, systematic investigations of these treatments, whether administered separately or together, would provide valuable insights into potential causal factors, which in turn could be used to further tailor treatment strategies.

(6) In order to take full advantage of the tremendous potential for finding a cure or effective treatment, Federal investment particularly for IBS and the FGIDs research must be increased by funding a number of experienced multidisciplinary clinical research and treatment centers on irritable bowel syndrome and FGIDs.

(7) The reason for focus of federal investment on the functional gastrointestinal disorders in particular relates to the larger body of scientific evidence that has accumulated to understand these conditions in addition to a stable scientific infrastructure of investigators poised to utilize this funding in their research programs and centers.

(8) Since the cause of IBS and the FGIDs are not fully understood and there is still no cure for them, basic research studies are focusing on the possible involvement of genetic and environmental factors, looking at receptors that cause improper transmission of nerve messages in the gut and the relationship of flare-ups to stressful or anxiety causing situations respectively.

(9) Given that such basic investigation may not yield benefits to patients for many years, it is critical that human research also be undertaken. It is important to place an emphasis on human research for these conditions that will generate results which have direct clinical relevance to patients.

(10) Therefore, these centers of excellence must have established multidisciplinary research and clinical expertise that involves translational science, clinical, behavioral and psychosocial methods and treatment approaches.

(11) Given their chronic nature, emphasis needs to be made for adequate scientific investigation to target the benefits of clinical and behavioral treatments to patients, as well as to train physicians in such methods to properly care for these patients.

(12) As research progresses, so do treatments for IBS and the FGIDs, however, reaching patients with treatment options has been stymied by an ambiguous approval and adverse event protocol at the Food and Drug Administration. The process must be clarified to ensure that industry continues to pursue the development of treatments.

### **SEC. 3 SENSE OF CONGRESS ON EXPANSION, INTENSIFICATION, AND COORDINATION OF RESEARCH ON IRRITABLE BOWEL SYNDROME AND FGIDs.**

It is the sense of Congress that –

- (1) the Secretary, acting through the Director of the National Institutes of Health and the National Institutes of Diabetes and Digestive and Kidney Diseases (in this section referred to as the “Institute”) should aggressively support expanded, intensified, and coordinated activities of the Institute with respect to research on IBS and the FGIDs, including by -
  - (A) conducting basic and clinical research into the cause, diagnosis, early detection, prevention, control, and treatment of such disorders;
  - (B) conducting clinically relevant studies on patient health outcomes and treatments that utilize behavioral and psychosocial approaches to improve those health outcomes;
  - (C) conducting training programs embedded in centers of excellence for scientists and health professionals to use clinical and behavioral methods that improve the physician patient relationship which leads to effective clinical outcomes;
  - (D) conducting programs to provide information and continuing education to health professionals; and
  - (E) conducting programs for the dissemination of information to the public;
- (2) the Director of the Institute should coordinate the activities of the Director under paragraph (1) with similar activities conducted by other national research institutes and agencies of the National Institutes of Health to the extent that such Institutes and agencies have responsibilities that are related to IBS and FGIDs;
- (3) in carrying out subsection (a), the Director of the Institute should make grants to, or enter into contracts with, public or nonprofit private entities for the development and operation of centers to conduct research and training to health care providers on IBS and FGIDs;
- (4) a center under paragraph (1) may use funds to provide stipends for scientists and health professionals enrolled in programs described in subparagraph (A)(ii) and (A)(iii).
- (5) the Director should, as appropriate, provide for the coordination of information among centers under paragraph (1) and ensure regular communication between such centers, and should require the periodic preparation of reports on the activities of the centers and the submission of the reports to the Director;

(6) each center under paragraph (1) should use the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such requirements as may be prescribed by the Director;

(7) the Director should, subject to the extent of amounts made available in appropriations acts, provide for the establishment of not less than three centers under paragraph (1). Support of such a center may be for a period not exceeding 5 years. Such period may be extended for one or more additional periods not exceeding 5 years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended;

(8) the Director of the Institute should establish a data system for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with IBS and FGIDs including, where possible, data involving general populations for the purpose of identifying individuals at risk of developing such condition.

(9) the Director of the Institute should establish an information clearinghouse to facilitate and enhance, through the effective dissemination of information, knowledge and understanding of irritable bowel syndrome and FGIDs by health professionals, patients, industry, and the public;

(10) in carrying out subsection (a), the Director of the Institute should provide for means through which the public can obtain information on the existing and planned programs and activities of the National Institutes of Health with respect to IBS and FGIDs, and through which the Director can receive comments from the public regarding such programs and activities;

(11) the Director of the Institute should prepare biennial reports on the activities conducted and supported under this section, and should include such reports in the biennial reports prepared by the Director under section 407.

#### **SEC. 4. THE CREATION OF A GUIDANCE DOCUMENT BY THE FOOD AND DRUG ADMINISTRATION ON THE APPROVAL CRITERIA FOR TREATMENTS OF IRRITABLE BOWEL SYNDROME.**

(a) Guidance Document - Not later than 12 months after the date of the enactment of this act the Commissioner of the Food and Drug Administration shall request from the Center for Drug Evaluation and Research a set of guidelines that will provide a clear pathway to industry on the standards for irritable bowel syndrome treatments, including the implication of adverse events that are reported during post-market surveillance.