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114TH CONGRESS
1ST SESSION

H. R. 2311

To expand the research activities of the National Institutes of Health with respect to functional gastrointestinal and motility disorders, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 13, 2015

Mr. SENSENBRENNER introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To expand the research activities of the National Institutes of Health with respect to functional gastrointestinal and motility disorders, and for other purposes.

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 ''Functional Gastrointestinal and Motility Disorders Research Enhancement Act of 2015''.

SEC. 2. FINDINGS.

Congress finds the following:

(1) Functional gastrointestinal and motility disorders (FGIMDs) are chronic conditions associated with increased sensitivity of the GI tract, abnormal motor functioning, and brain-gut dysfunction.

(2) FGIMDs are characterized by chronic or recurring symptoms in the GI tract including pain or discomfort, nausea, vomiting, diarrhea, constipation, incontinence, problems in the passage of food or feces, or a combination of these symptoms.

(3) FGIMDs include conditions such as functional dysphagia, gastroesophageal reflux disease, dyspepsia, cyclic vomiting syndrome, gallbladder and bile duct dysfunction, gastroparesis, irritable bowel syndrome (IBS), Hirschsprung's disease, chronic intestinal pseudo-obstruction, bowel incontinence, and many others, which affect the esophagus, stomach, gallbladder, small and large intestine, and anorectal areas of the body.

(4) The severity of FGIMDs ranges from mildly uncomfortable to debilitating and in some cases life-threatening.

(5) Effective treatments for the multiple symptoms of FGIMDs are lacking, and while sufferers frequently use a variety of medications and therapies

for symptoms, few patients report satisfaction with available treatments.

(6) Physicians are not sufficiently educated on the proper diagnosis and up-to-date treatments for FGIMDs. This leads to excess health care costs due to unneeded diagnostic procedures and errors in treatments.

(7) Patients with FGIMDs frequently suffer for years before receiving an accurate diagnosis, exposing them to unnecessary and costly tests and procedures including surgeries, as well as needless suffering and expense.

(8) The economic impact of FGIMDs is high. The annual cost in the United States for IBS alone is estimated to be between $1.7 billion and $10 billion in direct medical costs (excluding prescription and over-the-counter medications) and $20 billion in indirect medical costs.

(9) FGIMDs frequently take a toll on the workplace, as reflected in work absenteeism, lost productivity, and lost opportunities for the individual and society.

(10) Gastrointestinal symptoms consistent with functional gastrointestinal disorders, such as IBS and functional dyspepsia, are recognized as a serious

and disabling issue for military veterans, particularly those who have been deployed in war zones.

(11) FGIMDs affect individuals of all ages including children, and pediatric FGIMDs can be particularly serious, leading to a lifetime of painful symptoms and medical expenses associated with management of chronic illness or death.

(12) There is inadequate public education and misunderstanding of FGIMDs leading to stigma placed upon individuals so afflicted.

(13) The National Institutes of Health's National Commission on Digestive Diseases identified comprehensive research goals related to FGIMDs in its April 2009 report to Congress and the American public entitled ''Opportunities and Challenges in Digestive Diseases Research: Recommendations of the National Commission on Digestive Diseases''.

SEC. 3. FUNCTIONAL GASTROINTESTINAL AND MOTILITY DISORDERS RESEARCH ENHANCEMENT.

Part B of the title IV of the Public Health Service Act (42 U.S.C. 284 et seq.) is amended by adding at the end the following:

"SEC. 409K. FUNCTIONAL GASTROINTESTINAL AND MOTILITY DISORDERS.

''The Director of NIH may expand, intensify, and coordinate the activities of the National Institutes of Health with respect to functional gastrointestinal and motility disorders (in this section referred to as 'FGIMDs') by—

''(1) expanding basic and clinical research into FGIMDs by implementing the research recommendations of the National Commission on Digestive Diseases relating to FGIMDs;

''(2) providing support for the establishment of up to five centers of excellence on FGIMDs at leading academic medical centers throughout the country to carry out innovative basic, translational, and clinical research focused on FGIMDs;

''(3) supporting innovative approaches to educating health care providers and patients regarding strategies that improve patient-provider relationships and care and foster research to determine the effects of these approaches in improving patient satisfaction, improved clinical outcomes, efficient utilization of health care services, and reduced health care costs;

''(4) exploring collaborative research opportunities among the National Institute of Diabetes and Digestive and Kidney Diseases, the Office of Re-

search on Women's Health, the Office of Rare Disease Research, and other Institutes and Centers of the National Institutes of Health;

''(5) directing the National Institute of Diabetes and Digestive and Kidney Diseases to provide the necessary funding for continued expansion and advancement of the FGIMDs research portfolio through intramural and extramural research;

''(6) directing the National Institute of Diabetes and Digestive and Kidney Diseases and the Eunice Kennedy Shriver National Institute of Child Health and Human Development to expand research into FGIMDs that impact children, such as Hirschsprung's disease and cyclic vomiting syndrome, and maternal health, such as fecal incontinence; and

''(7) exploring opportunities to partner with the Department of Defense and the Department of Veterans Affairs to increase research and improve patient care regarding FGIMDs that commonly impact veterans and active duty military personnel, such as IBS and dyspepsia.''.

SEC. 4. PROMOTING PUBLIC AWARENESS OF FUNCTIONAL GASTROINTESTINAL AND MOTILITY DISORDERS.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by adding at the end the following:

"SEC. 320B. PUBLIC AWARENESS OF FUNCTIONAL GASTROINTESTINAL AND MOTILITY DISORDERS.

''The Secretary may engage in public awareness and education activities to increase understanding and recognition of functional gastrointestinal and motility disorders (in this section referred to as 'FGIMDs'). Such activities may include the distribution of print, film, and web-based materials targeting health care providers and the public and prepared and disseminated in conjunction with patient organizations that treat FGIMDs. The information expressed through such activities should emphasize—

''(1) basic information on FGIMDs, their symptoms, prevalence, and frequently co-occurring conditions; and

''(2) the importance of early diagnosis, and prompt and accurate treatment of FGIMDs.''.

SEC. 5. SENSE OF CONGRESS OF THE DEVELOPMENT AND OVERSIGHT OF INNOVATIVE TREATMENT OPTIONS FOR FUNCTIONAL GASTROINTESTINAL AND MOTILITY DISORDERS.

It is the sense of Congress that, considering the current lack of effective treatment options for the global symptoms of functional gastrointestinal and motility disorders (in this section referred to as ''FGIMDs'') and the inherent challenges of developing and bringing such treatments to market, the Commissioner of Food and Drugs should continue and accelerate important efforts to improve the development and oversight of treatment options for FGIMDs by—

(1) enhancing the commitment to emerging efforts like the Patient Reported Outcomes Consortium to expedite medical device and drug development, study appropriate balances between risk and patient benefit, and identify proper endpoints for conditions without clear, biological indicators;

(2) enhancing the commitment to broad efforts like the Critical Path Initiative focused on ensuring that scientific breakthroughs are quickly translated into safe and beneficial treatment options; and

(3) continuing collaboration with patient and provider organizations that treat FGIMDs so that

the patient perspective is considered when determining the need for innovative treatments.

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