

112TH CONGRESS
1ST SESSION

H. R. 2239

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

JUNE 16, 2011

Mr. SENSENBRENNER (for himself and Mr. MORAN) introduced the following bill; which was referred to the Committee on Energy and Commerce

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Functional Gastro-
5 intestinal and Motility Disorders Research Enhancement
6 Act of 2011”.

7 **SEC. 2. FINDINGS.**

8 Congress finds the following:

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

5 (2) FGIMDs are characterized by symptoms in
6 the GI tract including pain or discomfort, nausea,
7 vomiting, diarrhea, constipation, incontinence, prob-
8 lems in the passage of food or feces, or a combina-
9 tion of these symptoms.

10 (3) FGIMDs include conditions such as dys-
11 phagia, gastroesophageal reflux disease, dyspepsia,
12 cyclic vomiting syndrome, gastroparesis, irritable
13 bowel syndrome (IBS), Hirschsprung's disease,
14 chronic intestinal pseudo-obstruction, bowel inconti-
15 nence, and many others, which affect the esophagus,
16 stomach, gallbladder, small and large intestine, and
17 anorectal areas of the body.

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

21 (5) Effective treatments for the multiple symp-
22 toms of FGIMDs are lacking, and while sufferers
23 frequently use a variety of medications and therapies
24 for symptoms, few patients report satisfaction with
25 available treatments.

1 (6) Patients with FGIMDs frequently suffer for
2 years before receiving an accurate diagnosis, expos-
3 ing them to unnecessary and costly tests and proce-
4 dures including surgeries, as well as needless suf-
5 fering and expense.

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

12 (8) FGIMDs frequently take a toll on the work-
13 place, as reflected in work absenteeism, lost produc-
14 tivity, and lost opportunities for the individual and
15 society.

16 (9) Gastrointestinal symptoms consistent with
17 functional gastrointestinal disorders such as IBS
18 and functional dyspepsia have been recognized as a
19 serious and disabling issue for military veterans,
20 particularly those who have been deployed.

21 (10) FGIMDs affect individuals of all ages in-
22 cluding children, and pediatric FGIMDs can be par-
23 ticularly serious, leading to a lifetime of painful
24 symptoms and medical expenses associated with
25 management of chronic illness or death.

1 (11) The National Institutes of Health’s Na-
2 tional Commission on Digestive Diseases identified
3 comprehensive research goals related to FGIMDs in
4 its April 2009 report to Congress and the American
5 public entitled “Opportunities and Challenges in Di-
6 gestive Diseases Research: Recommendations of the
7 National Commission on Digestive Diseases”.

8 **SEC. 3. FUNCTIONAL GASTROINTESTINAL AND MOTILITY**
9 **DISORDERS RESEARCH ENHANCEMENT.**

10 Part B of title IV of the Public Health Service Act
11 (42 U.S.C. 284 et seq.) is amended by adding at the end
12 the following:

13 **“SEC. 409K. FUNCTIONAL GASTROINTESTINAL AND MOTIL-**
14 **ITY DISORDERS.**

15 “The Director of NIH may expand, intensify, and co-
16 ordinate the activities of the National Institutes of Health
17 with respect to functional gastrointestinal and motility dis-
18 orders (in this section referred to as ‘FGIMDs’) by—

19 “(1) expanding basic and clinical research into
20 FGIMDs by implementing the research rec-
21 ommendations of the National Commission on Di-
22 gestive Diseases relating to FGIMDs;

23 “(2) providing support for the establishment of
24 up to five centers of excellence on FGIMDs at lead-
25 ing academic medical centers throughout the country

1 to carry out innovative basic, translational, and clin-
2 ical research focused on FGIMDs;

3 “(3) exploring collaborative research opportuni-
4 ties among the National Institute of Diabetes and
5 Digestive and Kidney Diseases, the Office of Re-
6 search on Women’s Health, the Office of Rare Dis-
7 ease Research, and other Institutes and Centers of
8 the National Institutes of Health;

9 “(4) directing the National Institute of Diabe-
10 tes and Digestive and Kidney Diseases to provide
11 the necessary funding for continued expansion and
12 advancement of the FGIMDs research portfolio
13 through intramural and extramural research;

14 “(5) directing the National Institute of Diabe-
15 tes and Digestive and Kidney Diseases and the Eu-
16 nice Kennedy Shriver National Institute of Child
17 Health and Human Development to expand research
18 into FGIMDs that impact children, such as
19 Hirschsprung’s disease and cyclic vomiting syn-
20 drome, and maternal health, such as fecal inconti-
21 nence; and

22 “(6) exploring opportunities to partner with the
23 Department of Defense and the Department of Vet-
24 erans Affairs to increase research and improve pa-
25 tient care regarding FGIMDs that commonly impact

1 veterans and active duty military personnel, such as
2 IBS and dyspepsia.”.

3 **SEC. 4. PROMOTING PUBLIC AWARENESS OF FUNCTIONAL**
4 **GASTROINTESTINAL AND MOTILITY DIS-**
5 **ORDERS.**

6 Part B of title III of the Public Health Service Act
7 (42 U.S.C. 243 et seq.) is amended by adding at the end
8 the following:

9 **“SEC. 320B. PUBLIC AWARENESS OF FUNCTIONAL GASTRO-**
10 **INTESTINAL AND MOTILITY DISORDERS.**

11 “The Secretary may engage in public awareness and
12 education activities to increase understanding and recogni-
13 tion of functional gastrointestinal and motility disorders
14 (in this section referred to as ‘FGIMDs’). Such activities
15 may include the distribution of print, film, and web-based
16 materials targeting health care providers and the public
17 and prepared and disseminated in conjunction with pa-
18 tient organizations that treat FGIMDs. The information
19 expressed through such activities should emphasize—

20 “(1) basic information on FGIMDs, their symp-
21 toms, prevalence, and frequently co-occurring condi-
22 tions; and

23 “(2) the importance of early diagnosis, and
24 prompt and accurate treatment of FGIMDs.”.

1 **SEC. 5. SENSE OF CONGRESS ON THE DEVELOPMENT AND**
2 **OVERSIGHT OF INNOVATIVE TREATMENT OP-**
3 **TIONS FOR FUNCTIONAL GASTROINTESTINAL**
4 **AND MOTILITY DISORDERS.**

5 It is the sense of Congress that, considering the cur-
6 rent lack of effective treatment options for the global
7 symptoms of functional gastrointestinal and motility dis-
8 orders (in this section referred to as “FGIMDs”) and the
9 inherent challenges of developing and bringing such treat-
10 ments to market, the Commissioner of Food and Drugs
11 should continue and accelerate important efforts to im-
12 prove the development and oversight of treatment options
13 for FGIMDs by—

14 (1) enhancing the commitment to emerging ef-
15 forts like the Patient Reported Outcomes Consor-
16 tium to expedite medical device and drug develop-
17 ment, study appropriate balances between risk and
18 patient benefit, and identify proper endpoints for
19 conditions without clear, biological indicators;

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

24 (3) continuing collaboration with patient orga-
25 nizations that treat FGIMDs so that the patient

- 1 perspective is considered when determining the need
- 2 for innovative treatments.

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