

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

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 2015”.

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 chronic or re-
6 curring symptoms in the GI tract including pain or
7 discomfort, nausea, vomiting, diarrhea, constipation,
8 incontinence, problems in the passage of food or
9 feces, or a combination of these symptoms.

10 (3) FGIMDs include conditions such as func-
11 tional dysphagia, gastroesophageal reflux disease,
12 dyspepsia, cyclic vomiting syndrome, gallbladder and
13 bile duct dysfunction, gastroparesis, irritable bowel
14 syndrome (IBS), Hirschsprung's disease, chronic in-
15 testinal pseudo-obstruction, bowel incontinence, and
16 many others, which affect the esophagus, stomach,
17 gallbladder, small and large intestine, and anorectal
18 areas of the body.

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

22 (5) Effective treatments for the multiple symp-
23 toms of FGIMDs are lacking, and while sufferers
24 frequently use a variety of medications and therapies

1 for symptoms, few patients report satisfaction with
2 available treatments.

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

8 (7) Patients with FGIMDs frequently suffer for
9 years before receiving an accurate diagnosis, expos-
10 ing them to unnecessary and costly tests and proce-
11 dures including surgeries, as well as needless suf-
12 fering and expense.

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

19 (9) FGIMDs frequently take a toll on the work-
20 place, as reflected in work absenteeism, lost produc-
21 tivity, and lost opportunities for the individual and
22 society.

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

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

3 (11) FGIMDs affect individuals of all ages in-
4 cluding children, and pediatric FGIMDs can be par-
5 ticularly serious, leading to a lifetime of painful
6 symptoms and medical expenses associated with
7 management of chronic illness or death.

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

11 (13) The National Institutes of Health's Na-
12 tional Commission on Digestive Diseases identified
13 comprehensive research goals related to FGIMDs in
14 its April 2009 report to Congress and the American
15 public entitled "Opportunities and Challenges in Di-
16 gestive Diseases Research: Recommendations of the
17 National Commission on Digestive Diseases".

18 **SEC. 3. FUNCTIONAL GASTROINTESTINAL AND MOTILITY**

19 **DISORDERS RESEARCH ENHANCEMENT.**

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

1 **“SEC. 409K. FUNCTIONAL GASTROINTESTINAL AND MOTIL-**
2 **ITY DISORDERS.**

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

7 “(1) expanding basic and clinical research into
8 FGIMDs by implementing the research rec-
9 ommendations of the National Commission on Di-
10 gestive Diseases relating to FGIMDs;

11 “(2) providing support for the establishment of
12 up to five centers of excellence on FGIMDs at lead-
13 ing academic medical centers throughout the country
14 to carry out innovative basic, translational, and clin-
15 ical research focused on FGIMDs;

16 “(3) supporting innovative approaches to edu-
17 cating health care providers and patients regarding
18 strategies that improve patient-provider relationships
19 and care and foster research to determine the effects
20 of these approaches in improving patient satisfac-
21 tion, improved clinical outcomes, efficient utilization
22 of health care services, and reduced health care
23 costs;

24 “(4) exploring collaborative research opportuni-
25 ties among the National Institute of Diabetes and
26 Digestive and Kidney Diseases, the Office of Re-

1 search on Women’s Health, the Office of Rare Dis-
2 ease Research, and other Institutes and Centers of
3 the National Institutes of Health;

4 “(5) directing the National Institute of Diabe-
5 tes and Digestive and Kidney Diseases to provide
6 the necessary funding for continued expansion and
7 advancement of the FGIMDs research portfolio
8 through intramural and extramural research;

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

17 “(7) exploring opportunities to partner with the
18 Department of Defense and the Department of Vet-
19 erans Affairs to increase research and improve pa-
20 tient care regarding FGIMDs that commonly impact
21 veterans and active duty military personnel, such as
22 IBS and dyspepsia.”.

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

4 Part B of title III of the Public Health Service Act
5 (42 U.S.C. 243 et seq.) is amended by adding at the end
6 the following:

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

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

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

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

1 **SEC. 5. SENSE OF CONGRESS OF 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 and
25 provider organizations that treat FGIMDs so that

- 1 the patient perspective is considered when deter-
- 2 mining the need for innovative treatments.

