

.....
(Original Signature of Member)

116TH CONGRESS
1ST SESSION

H. R.

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

Mr. SENSENBRENNER introduced the following bill; which was referred to the Committee on _____

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 2019”.

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 both common and rare
11 conditions, such as functional dysphagia,
12 gastroesophageal reflux disease, dyspepsia, cyclic
13 vomiting syndrome, gallbladder and bile duct dys-
14 function, gastroparesis, irritable bowel syndrome
15 (IBS), Hirschsprung's disease, chronic intestinal
16 pseudo-obstruction, bowel incontinence, opioid in-
17 duced GI hyperalgesia, abdomino-phrenic
18 dyssynergia (APD), and many others, which affect
19 the esophagus, stomach, gallbladder, small and large
20 intestine, and anorectal areas of the body.

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

24 (5) Effective treatments for the multiple symp-
25 toms of FGIMDs are lacking, and while sufferers

1 frequently use a variety of medications and therapies
2 for symptoms, few patients report satisfaction with
3 available treatments.

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

9 (7) Frequently there is a need for a multidisci-
10 plinary care approach to patients with FGIMDs, in-
11 cluding access to nutritional and mental health sup-
12 port to improve pain management and facilitate pa-
13 tient and parent understanding of the brain-gut axis
14 and overall patient functioning.

15 (8) Patients with FGIMDs frequently suffer for
16 years before receiving an accurate diagnosis, expos-
17 ing them to unnecessary and costly tests and proce-
18 dures including surgeries, as well as needless suf-
19 fering and expense.

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

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

5 (11) Gastrointestinal symptoms consistent with
6 functional gastrointestinal disorders, such as IBS
7 and functional dyspepsia, are recognized as a serious
8 and disabling issue for military veterans, particularly
9 those who have been deployed in war zones and ex-
10 perience posttraumatic stress disorder.

11 (12) FGIMDs affect individuals of all ages in-
12 cluding children, and pediatric FGIMDs can be par-
13 ticularly serious, leading to a lifetime of painful
14 symptoms and medical expenses associated with
15 management of chronic illness or death, as well as
16 missed school days and homebound instruction.

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

20 (14) The National Institutes of Health's Na-
21 tional Commission on Digestive Diseases identified
22 comprehensive research goals related to FGIMDs in
23 its April 2009 report to Congress and the American
24 public entitled "Opportunities and Challenges in Di-

1 gestive Diseases Research: Recommendations of the
2 National Commission on Digestive Diseases”.

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

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

8 **“SEC. 409K. FUNCTIONAL GASTROINTESTINAL AND MOTIL-**
9 **ITY DISORDERS.**

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

14 “(1) expanding basic and clinical research into
15 FGIMDs by implementing the research rec-
16 ommendations of the National Commission on Di-
17 gestive Diseases relating to FGIMDs;

18 “(2) providing support for the establishment of
19 up to 5 centers of excellence on FGIMDs at leading
20 academic medical centers throughout the country to
21 carry out innovative basic, translational, and clinical
22 research focused on FGIMDs in both pediatric and
23 adult patients;

24 “(3) supporting innovative approaches to edu-
25 cating health care providers and patients regarding

1 strategies that improve patient-provider relationships
2 and care and foster research to determine the effects
3 of these approaches in improving patient satisfac-
4 tion, improved clinical outcomes, efficient utilization
5 of health care services, and reduced health care
6 costs;

7 “(4) exploring collaborative research opportuni-
8 ties among the National Institute of Diabetes and
9 Digestive and Kidney Diseases, the Office of Re-
10 search on Women’s Health, the Office of Rare Dis-
11 eases, the National Institute of Mental Health, and
12 other institutes and centers of the National Insti-
13 tutes of Health;

14 “(5) directing the National Institute of Diabe-
15 tes and Digestive and Kidney Diseases to provide
16 the necessary funding for continued expansion and
17 advancement of the FGIMDs research portfolio
18 through intramural and extramural research;

19 “(6) directing the National Institute of Diabe-
20 tes and Digestive and Kidney Diseases and the Eu-
21 nice Kennedy Shriver National Institute of Child
22 Health and Human Development to expand research
23 into FGIMDs that impact children, such as
24 Hirschsprung’s disease and cyclic vomiting syn-

1 drome, and maternal health, such as fecal inconti-
2 nence; and

3 “(7) exploring opportunities to partner with the
4 Department of Defense and the Department of Vet-
5 erans Affairs to increase research and improve pa-
6 tient care regarding FGIMDs that commonly impact
7 veterans and active duty military personnel, such as
8 IBS and dyspepsia.”.

9 **SEC. 4. PROMOTING PUBLIC AWARENESS OF FUNCTIONAL**
10 **GASTROINTESTINAL AND MOTILITY DIS-**
11 **ORDERS.**

12 Part B of title III of the Public Health Service Act
13 (42 U.S.C. 243 et seq.) is amended by adding at the end
14 the following:

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

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

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

4 “(2) the importance of early diagnosis, and
5 prompt and accurate treatment of FGIMDs, includ-
6 ing access to nutritional and mental health sup-
7 port.”.

8 **SEC. 5. SENSE OF CONGRESS OF THE DEVELOPMENT AND**
9 **OVERSIGHT OF INNOVATIVE TREATMENT OP-**
10 **TIONS FOR FUNCTIONAL GASTROINTESTINAL**
11 **AND MOTILITY DISORDERS.**

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

21 (1) enhancing the commitment to emerging ef-
22 forts like the Patient Reported Outcomes Consor-
23 tium to expedite medical device and drug develop-
24 ment, the study of appropriate balances between risk
25 and patient benefit, and identification of proper

1 endpoints for conditions without clear, biological in-
2 dicators;

3 (2) enhancing the commitment to broad efforts
4 like the Critical Path Initiative focused on ensuring
5 that scientific breakthroughs are quickly translated
6 into safe and beneficial treatment options for both
7 pediatric and adult patients; and

8 (3) continuing collaboration with patient and
9 provider organizations that treat FGIMDs so that
10 the patient perspective is considered when deter-
11 mining the need for innovative treatments.