108TH CONGRESS 2D SESSION

H. R. 4979

To amend the Public Health Service Act to provide for educational activities and research with respect to women's pelvic floor health through the Centers for Disease Control and Prevention and the National Institutes of Health.

IN THE HOUSE OF REPRESENTATIVES

July 22, 2004

Mr. Nethercutt (for himself, Mrs. Davis of California, Mr. Gerlach, Mr. Sessions, and Mr. Vitter) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Public Health Service Act to provide for educational activities and research with respect to women's pelvic floor health through the Centers for Disease Control and Prevention and the National Institutes of Health.

- 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 "Women's Pelvic Floor
- 5 Health Education and Awareness Act".
- 6 SEC. 2. FINDINGS.
- 7 The Congress finds as follows:

- 1 (1) Women's pelvic floor disorders are a group 2 of common conditions that cause considerable dis-3 ability and pain.
 - (2) Such disorders include bladder and bowel dysfunction, including incontinence. Another such disorder is pelvic organ prolapse, which involves a downward shift of uterine or vaginal structures from their normal positions. Often these conditions coexist.
 - (3) Women's pelvic floor disorders are extremely common and are barriers to healthy living.
 - (4) Women often suffer from a broad overlap of all pelvic floor disorders, usually experiencing several disorders simultaneously.
 - (5) Thirty percent of American women will suffer from a form of urinary incontinence.
 - (6) Eleven percent of women in the United States have surgery for urinary incontinence or pelvic organ prolapse during their lifetime, and close to one third will have a second surgery. Many more women are treated with nonsurgical techniques or remain untreated.
 - (7) Of the 3 million vaginal deliveries that occur each year in the United States, 900,000 women will develop symptomatic urinary inconti-

- nence and a smaller number will develop pelvic
 organ prolapse and bowel incontinence.
- 3 (8) An estimated \$26.3 billion is spent annually 4 to either treat or compensate for urinary inconti-5 nence.
- 6 (9) Many health care providers are not pre-7 pared to evaluate urinary pelvic floor disorders, in-8 cluding incontinence, and are unaware of treatment 9 options.
- 10 (10) To address the public health threat posed 11 by women's pelvic floor disorders, there is a need for 12 the establishment of awareness and education pro-13 grams directed at the public and primary-care pro-14 viders, including the authorization of research fo-15 cused on urinary incontinence and other pelvic floor 16 disorders. Such programs will greatly help promote 17 better care and treatment to those women afflicted 18 with these disorders.

19 SEC. 3. EDUCATION REGARDING WOMEN'S PELVIC FLOOR

- 20 **DISORDERS.**
- 21 (a) IN GENERAL.—Part P of title III of the Public
- 22 Health Service Act (42 U.S.C. 280g et seq.) is amended
- 23 by adding at the end the following section:

1	"SEC. 3990. EDUCATION REGARDING WOMEN'S PELVIC
2	FLOOR DISORDERS.
3	"(a) In General.—The Secretary, acting through
4	the Administrator of the Health Resources and Services
5	Administration and the Director of the Centers for Dis-
6	ease Control and Prevention, shall carry out a program
7	to provide education regarding bladder and bowel dysfunc-
8	tion (including incontinence), pelvic organ prolapse, and
9	other pelvic floor disorders to health professionals and the
10	general public. Activities under such program shall be car-
11	ried out directly by the Secretary and through awards of
12	grants or contracts to States, political subdivisions of
13	States, and other public or nonprofit private entities.
14	"(b) Certain Information.—The Secretary shall
15	ensure that education under subsection (a) includes, at a
16	minimum—
17	"(1) information describing the prevalence of
18	pelvic floor disorders in women; and
19	"(2) information regarding treatment options
20	for such disorders.
21	"(c) USE OF INTERNET.—The Secretary shall ensure
22	that the means through which education under subsection
23	(a) is provided includes the posting of information on the
24	Internet site of the Centers for Disease Control and Pre-
25	vention. The Secretary shall ensure that, in the case of

- 1 health professionals, such means includes means in addi-
- 2 tion to the posting of information on such site.
- 3 "(d) AUTHORIZATION OF APPROPRIATIONS.—For the
- 4 purpose of carrying out this section, there are authorized
- 5 to be appropriated such sums as may be necessary for
- 6 each of the fiscal years 2005 through 2009.".
- 7 (b) Sense of Congress.—It is the sense of the
- 8 Congress that the Director of the Centers for Disease
- 9 Control and Prevention should establish a national reg-
- 10 istry for surgical treatment of pelvic floor disorders, espe-
- 11 cially procedures using new technology.
- 12 SEC. 4. RESEARCH THROUGH NATIONAL INSTITUTES OF
- HEALTH.
- 14 (a) IN GENERAL.—Part B of title IV of the Public
- 15 Health Service Act (42 U.S.C. 284 et seq.) is amended
- 16 by adding at the end the following:
- 17 "SEC. 409J. WOMEN'S PELVIC FLOOR DISORDERS.
- 18 "(a) In General.—The Directors of the National
- 19 Institute of Diabetes and Digestive and Kidney Diseases
- 20 and the National Institute of Child Health and Human
- 21 Development shall expand and intensify the activities of
- 22 such Institutes with respect to women's pelvic floor dis-
- 23 orders, including proposals for research on such disorders
- 24 that are developed independently of solicitations by the
- 25 National Institutes of Health for research proposals.

"(b) Networks.—

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"(1) Urinary INCONTINENCE TREATMENT NETWORK.—The Director of the National Institute of Diabetes and Digestive and Kidney Diseases, in consultation with the Director of the National Institute of Child Health and Human Development, shall provide for the continuing operation of the Urinary Incontinence Treatment Network. The Network was established pursuant to financial awards from such Institutes, and includes multiple continence treatment centers and a single biostatistical coordinating committee. The Director shall ensure that not fewer than eight such treatment centers are in operation and may provide for the establishment of additional treatment centers, subject to appropriations Acts.

"(2) CLINICAL TRIALS NETWORK FOR FEMALE PELVIC DISORDERS.—The Director of the National Institute of Child Health and Human Development, in consultation with the Director of the National Institute of Diabetes and Digestive and Kidney Diseases, shall provide for the continuing operation of the Clinical Trials Network for Female Pelvic Disorders. The Network was established pursuant to financial awards from such Institutes, and includes multiple clinical sites and a single data coordinating

1	committee. The Director shall ensure that not fewer
2	than seven such clinical sites are in operation and
3	may provide for the establishment of additional clin-
4	ical sites, subject to appropriations Acts.
5	"(c) Peer Review.—With respect to technical and
6	scientific peer review under section 492, the Director of
7	NIH shall ensure that groups that review research pro-
8	posals under this section include urogynecologists. ".
9	(b) Sense of Congress.—
10	(1) In general.—The Congress commends—
11	(A) the National Institute of Diabetes and
12	Digestive and Kidney Diseases for its financial
13	support of the Urinary Incontinence Treatment
14	Network;
15	(B) the National Institute of Child Health
16	and Human Development for its financial sup-
17	port of the Clinical Trials Network for Female
18	Pelvic Disorders;
19	(C) the successful collaboration of such In-
20	stitutes with respect to the Networks; and
21	(D) each of such Networks for the re-
22	search it is conducting toward improving wom-
23	en's pelvic health.
24	(2) CERTAIN ACTIVITIES.—It is the sense of the
25	Concress that the Directors of the National Institute

1	of Diabetes and Digestive and Kidney Diseases and
2	the National Institute of Child Health and Human
3	Development should—
4	(A) increase the size, scope, number, and
5	funding for multidisciplinary research through
6	centers and clinical sites of the Networks re-
7	ferred to in paragraph (1);
8	(B) encourage industry relationships in
9	women's pelvic floor health related research;
10	(C) recruit established scientists from
11	other relevant areas (such as cardiac or gastro-
12	intestinal physiology, cell signaling, biomechan-
13	ical engineering, genomics, and proteomics) to
14	apply their work to the urinary tract and incon-
15	tinence by encouraging collaborative efforts be-
16	tween basic and clinical scientists;
17	(D) increase research funding for studies
18	that use cellular and molecular techniques to
19	examine the basic mechanisms of bladder and
20	urethral interactions that create urinary con-
21	tinence and incontinence;
22	(E) support research to develop appro-
23	priate animal models of urinary incontinence;
24	(F) develop novel techniques (both invasive
25	and noninvasive) for measuring neural, mus-

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1	cular (striated and smooth), and vascular func-
2	tion relating to pelvic floor health;
3	(G) identify risk factors for pelvic floor dis-
4	orders and urinary incontinence related to
5	childbirth and aging so that prevention meas
6	ures and improved disease-specific treatment
7	can be developed;
8	(H) initiate research to develop preventive
9	and therapeutic approaches to urinary inconti-
10	nence that are sensitive to gender, race, and
11	culture, and develop the means of measuring
12	outcomes for treatments in these varied set
13	$\operatorname{tings};$
14	(I) develop a national data registry and tis-
15	sue bank of people suffering from incontinence
16	to meet the needs of researchers for well-char-
17	acterized tissue samples; and
18	(J) research the relationship between the
19	anatomic changes of pelvic organ prolapse and

(J) research the relationship between the anatomic changes of pelvic organ prolapse and the functional derangement's commonly seen in association with them, including voiding dysfunction and incontinence.

SEC. 5. INCLUSION OF WOMEN'S PELVIC FLOOR HEALTH IN

- 2 NATIONAL CHILDREN'S STUDY.
- 3 The Director of the National Institute of Child
- 4 Health and Human Development shall include women's
- 5 pelvic floor health as one of the matters studied in the
- 6 prospective cohort study regarding child health and
- 7 human development that is being conducted under section
- 8 1004(b) of the Children's Health Act of 2000 (Public Law
- 9 106–310; 114 Stat. 1130) and is known as the National
- 10 Children's Study.
- 11 SEC. 6. CONSULTATION.
- 12 In carrying out this Act, the Secretary of Health and
- 13 Human Services shall consult with the American
- 14 Urogynecologic Society and such other qualified profes-
- 15 sional and patient organizations as the Secretary deter-
- 16 mines to be appropriate.

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