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S. 4533

To expand and promote research and data collection on reproductive health conditions, to provide training opportunities for medical professionals to learn how to diagnose and treat reproductive health conditions, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JUNE 13, 2024

Mrs. HYDE-SMITH (for herself, Mr. LANKFORD, Mr. CORNYN, Mr. WICKER, Mr. RICKETTS, Mr. MULLIN, and Mr. GRASSLEY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To expand and promote research and data collection on reproductive health conditions, to provide training opportunities for medical professionals to learn how to diagnose and treat reproductive health conditions, 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 “Reproductive Em-
5 powerment and Support through Optimal Restoration
6 Act” or the “RESTORE Act”.

1 **SEC. 2. FINDINGS.**

2 Congress finds the following:

3 (1) In vitro fertilization and other assisted re-
4 productive technologies are not under threat at the
5 Federal level or in any State or territory of the
6 United States.

7 (2) There is a growing interest among women
8 to proactively assess their overall health and under-
9 stand how factors such as age and medical history
10 contribute to reproductive health and fertility.

11 (3) Women are worthy of the highest standard
12 of medical care, including the opportunity to assess,
13 understand, and improve their reproductive health.
14 Unfortunately, many women do not receive adequate
15 information about their reproductive health and do
16 not have access to restorative reproductive medicine.

17 (4) Reproductive health conditions are the lead-
18 ing causes of infertility, which affects 15 to 16 per-
19 cent of couples in the United States. Such conditions
20 include the following:

21 (A) Endometriosis, a disease where tissue
22 resembling endometrial lining tissue grows out-
23 side of the uterus. The tissue often adheres to
24 different organs, disfiguring them and, through
25 scar tissue or adhesions, can make the organs
26 stick to one another or to the pelvic walls. It

1 has been found in the abdominal organs, the
2 bowel, the diaphragm, the lungs, the brain, and
3 the eye. It is a progressive disease and has been
4 compared to growing like cancer. Endometriosis
5 is often diagnosed in stages, with Stage I as the
6 mildest form and Stage IV as the most severe
7 and widespread form. The average diagnosis
8 delay for endometriosis is 6 to 12 years. Endo-
9 metriosis frequently goes undiagnosed, and
10 women may suffer for years with painful peri-
11 ods, pelvic pain, or infertility. The cause of
12 endometriosis is unknown.

13 (B) Adenomyosis, a disease that occurs
14 when endometrial tissue (tissue that would nor-
15 mally line the inside of the uterus) grows into
16 the muscle layer of the uterus. Adenomyosis is
17 different from, but can exist concurrently with,
18 endometriosis. Adenomyosis may increase the
19 risk of miscarriage and preterm labor and may
20 contribute to infertility. The cause of
21 adenomyosis is unknown.

22 (C) Polycystic ovary syndrome, a reproduc-
23 tive hormonal disorder that causes cysts to
24 grow on the ovaries, usually as a result of hor-
25 monal imbalances. Polycystic ovary syndrome

1 affects approximately 15 percent of women
2 overall but is more common among women with
3 infertility. It is more prevalent among women
4 with obesity and insulin resistance. Women with
5 polycystic ovary syndrome who are trying to
6 achieve pregnancy are commonly prescribed oral
7 ovulation medication and hormonal injections
8 that stimulate ovulation. Effective diagnosis
9 and treatment exist, and should be made avail-
10 able for all women. Accurate and timely diag-
11 nosis and treatment can correct underlying hor-
12 monal imbalances, critical for both long-term
13 health improvements as well as for fertility out-
14 comes.

15 (D) Uterine fibroids, which are muscular
16 tumors that grow in the wall of the uterus.
17 While not all women will experience symptoms
18 associated with fibroids, if the tumors are large
19 enough or embedded far enough in the uterine
20 lining, they can lead to pain and heavy bleed-
21 ing. Treatment for fibroids may include assess-
22 ment of underlying hormonal imbalances,
23 hysteroscopic myomectomy, abdominal
24 myomectomy, uterine fibroid embolization, and
25 uterine artery embolization. Uterine fibroids

1 can increase risks of preterm labor, pregnancy
2 complications leading to a cesarean section, and
3 placental abruption, among other risks. The
4 cause of uterine fibroids is unknown.

5 (E) Blocked fallopian tubes, a condition
6 where the fallopian tubes are blocked by tubal
7 spasm, scarring from inflammatory conditions,
8 debris, tubal polyps, tubal ligation, prior ectopic
9 pregnancy, pelvic adhesions, endometriosis,
10 prior pelvic infection (pelvic inflammatory dis-
11 ease or “PID”). Approximately 1 in 4 women
12 with infertility have a tubal blockage. This con-
13 dition makes achieving pregnancy difficult, if
14 not impossible. Treatments for a blockage in-
15 clude fallopian tube recanalization, tubo-tubal
16 anastomosis (tubal ligation reversal), or
17 neosalpingostomy/fimbrioplasty.

18 (5) Research shows 4 or more conditions or fac-
19 tors are the cause of most male and female infer-
20 tility.

21 (6) There is a gap in research and care for
22 male and female reproductive health conditions,
23 which affect many Americans struggling with unex-
24 plained infertility.

1 (7) Restorative reproductive medicine aims to
2 diagnose and treat underlying hormonal and other
3 imbalances, restore health where possible, and im-
4 prove women’s health functioning and long-term out-
5 comes.

6 (8) Restorative reproductive medicine can elimi-
7 nate barriers to successful conception, pregnancy,
8 and birth. It can also address some causes of recur-
9 rent miscarriages.

10 (9) Restorative reproductive medicine often alle-
11 viates other difficult symptoms associated with re-
12 productive health conditions, including hormonal
13 acne, hormonal weight gain, hormonal mood and de-
14 pression, painful periods, painful flare-ups, bloating,
15 inflammation, heavy periods, irregular periods, nerve
16 pain, bowel symptoms, pain during sexual inter-
17 course, and back pain.

18 **SEC. 3. DEFINITIONS.**

19 In this Act:

20 (1) ASSISTED REPRODUCTIVE TECHNOLOGY.—
21 The term “assisted reproductive technology” means
22 any treatments or procedures that involve the han-
23 dling of a human egg, sperm, and embryo outside of
24 the body with the intent of facilitating a pregnancy,
25 including artificial insemination, intrauterine insemi-

1 nation, in vitro fertilization, gamete intrafallopian
2 fertilization, zygote intrafallopian fertilization, egg,
3 embryo, and sperm cryopreservation, and egg or em-
4 bryo donation.

5 (2) FERTILITY AWARENESS-BASED METHODS.—

6 The term “fertility awareness-based methods”
7 means modern, evidence-based methods of tracking
8 the menstrual cycle through observable biological
9 signs in a woman, such as body temperature, cer-
10 vical fluid, and hormone production in the reproduc-
11 tive system, including luteinizing hormone (LH) and
12 estrogen. Such methods include Fertility Education
13 and Medical Management, the sympto thermal meth-
14 od, the Marquette method, the Creighton method,
15 and the Billings ovulation method.

16 (3) FERTILITY EDUCATION AND MEDICAL MAN-

17 AGEMENT.—The term “fertility education and med-
18 ical management” means the program developed in
19 collaboration with the Reproductive Health Research
20 Institute for medical research, protocols, and med-
21 ical training for health care professionals in order to
22 enable the clinical application of important research
23 advances in reproductive endocrinology, by providing
24 education for women about their bodies and hor-
25 monal health and medical support, as appropriate.

1 (4) INFERTILITY.—The term “infertility”
2 means a symptom of an underlying disease or condi-
3 tion within a person’s body that makes it difficult or
4 impossible to successfully conceive and carry a child
5 to term, which is diagnosed after 12 months of
6 intercourse without the use of a chemical, barrier, or
7 other contraceptive method for women under 35 or
8 after 6 months of targeted intercourse without the
9 use of a chemical, barrier, or other contraceptive
10 method for women 35 and older, where conception
11 should otherwise be possible.

12 (5) NATURAL PROCREATIVE TECHNOLOGY;
13 NAPROTECHNOLOGY.—The term “Natural Pro-
14 creative Technology” or “NaProTECHNOLOGY”
15 means an approach to health care that monitors and
16 maintains a woman’s reproductive and gynecological
17 health, including laparoscopic gynecologic surgery to
18 reconstruct the uterus, fallopian tubes, ovaries, and
19 other organ structures to eliminate endometriosis
20 and other reproductive health conditions.

21 (6) REPRODUCTIVE HEALTH CONDITIONS.—
22 The term “reproductive health conditions” includes
23 endometriosis, adenomyosis, polycystic ovary syn-
24 drome, uterine fibroids, blocked fallopian tubes, hor-
25 mone imbalances, hyperprolactinemia, thyroid condi-

1 tions, ovulation dysfunctions, and other health condi-
2 tions that make it difficult or impossible to success-
3 fully conceive a child where conception should other-
4 wise be possible.

5 (7) RESTORATIVE REPRODUCTIVE HEALTH.—

6 The term “restorative reproductive health” includes
7 empowering women and men to know and under-
8 stand their bodies and appreciate the importance of
9 natural reproductive health to overall health and
10 well-being, including through the use of body literacy
11 programs that incorporate science-based charting
12 methods, teacher lead reproductive health education,
13 restorative reproductive medicine, Natural Pro-
14 creative Technology, fertility awareness-based meth-
15 ods, and fertility education and medical manage-
16 ment.

17 (8) RESTORATIVE REPRODUCTIVE MEDICINE.—

18 The term “restorative reproductive medicine”—

19 (A) means any scientific approach to re-
20 productive medicine that seeks to cooperate
21 with, or restore the normal physiology and
22 anatomy of, the human reproductive system,
23 without the use of methods that are inherently
24 suppressive, circumventive, or destructive to
25 natural human functions; and

1 (B) may include ultrasounds, blood tests,
2 hormone panels, laparoscopic and exploratory
3 surgeries, examining the man's or woman's
4 overall health and lifestyle, eliminating environ-
5 mental endocrine disruptors, and assessing the
6 health and fertility of the individual's partner,
7 Natural Procreative Technology, fertility aware-
8 ness-based methods, and fertility education and
9 medical management.

10 **SEC. 4. PROHIBITING DISCRIMINATION AGAINST HEALTH**
11 **CARE PROVIDERS WHO DO NOT PARTICIPATE**
12 **IN ASSISTED REPRODUCTIVE TECHNOLOGY.**

13 Notwithstanding any other law, the Federal Govern-
14 ment, and any person or entity that receives Federal fi-
15 nancial assistance, including any State or local govern-
16 ment, may not penalize, retaliate against, or otherwise dis-
17 criminate against a health care provider on the basis that
18 the provider does not or declines to—

19 (1) assist in, receive training in, provide, per-
20 form, refer for, pay for, or otherwise participate in
21 assisted reproductive technology; or

22 (2) facilitate or make arrangements for any of
23 the activities specified in paragraph (1) in a manner
24 that violates the provider's sincerely held religious
25 beliefs or moral convictions.

1 **SEC. 5. IMPLEMENTING LITERATURE REVIEWS ON THE**
2 **STANDARD OF CARE FOR THE DIAGNOSIS OF**
3 **INFERTILITY.**

4 (a) IN GENERAL.—The Assistant Secretary for
5 Health of the Department of Health and Human Services
6 (referred to in this section as the “Assistant Secretary”)
7 shall collect data on the topics described in subsection (b)
8 and, not later than 2 years after the date of enactment
9 of this Act and every 3 years thereafter, issue a report
10 on the standard of care for women who have been diag-
11 nosed with infertility.

12 (b) TOPICS.—In carrying out subsection (a), the As-
13 sistant Secretary shall—

14 (1) assess peer-reviewed studies on referrals to
15 restorative reproductive medicine that are given
16 prior to referrals for or use of assisted reproductive
17 technology;

18 (2) assess peer-reviewed studies related to ac-
19 cess to patient and health care provider information
20 and training for fertility awareness-based methods;
21 and

22 (3) assess the extent to which the treatments,
23 tests, and training described in paragraphs (1) and
24 (2) are covered under public and private health
25 plans.

1 (c) **PRIVACY REQUIREMENTS.**—In carrying out sub-
 2 section (a), the Assistant Secretary shall ensure that the
 3 privacy and confidentiality of individual patients are pro-
 4 tected in a manner consistent with relevant privacy and
 5 confidentiality law.

6 **SEC. 6. IMPLEMENTING LITERATURE REVIEWS ON THE**
 7 **STANDARD OF CARE FOR WOMEN SEEKING A**
 8 **REPRODUCTIVE HEALTH CONDITION DIAG-**
 9 **NOSIS.**

10 (a) **IN GENERAL.**—The Assistant Secretary for
 11 Health of the Department of Health and Human Services
 12 (referred to in this section as the “Assistant Secretary”)
 13 shall collect data on the topics described in subsection (b)
 14 and, not later than 2 years after the date of enactment
 15 of this Act and every 3 years thereafter, issue a report
 16 on the standard of care for women seeking reproductive
 17 health condition diagnoses.

18 (b) **TOPICS.**—In carrying out paragraph (1), the As-
 19 sistant Secretary shall—

20 (1) assess peer-reviewed studies related to ac-
 21 cess to restorative reproductive medicine and restor-
 22 ative reproductive health, including access to medical
 23 professionals trained in NaProTechnology and fer-
 24 tility education and medical management;

1 (2) assess peer-reviewed studies related to ac-
2 cess to information and training on fertility aware-
3 ness-based methods; and

4 (3) assess the extent to which the treatments,
5 tests, and training described in paragraphs (1) and
6 (2) are covered under public and private health
7 plans.

8 (c) PRIVACY REQUIREMENTS.—In carrying out sub-
9 section (a), the Assistant Secretary shall ensure that the
10 privacy and confidentiality of individual patients are pro-
11 tected in a manner consistent with relevant privacy and
12 confidentiality law.

13 **SEC. 7. EXPANDING THE NATIONAL SURVEY OF FAMILY**
14 **GROWTH TO INCLUDE REPRODUCTIVE**
15 **HEALTH CONDITIONS, RESTORATIVE REPRO-**
16 **DUCTIVE MEDICINE, AND FERTILITY AWARE-**
17 **NESS-BASED METHODS.**

18 (a) IN GENERAL.—The Director of the Centers for
19 Disease Control and Prevention (referred to in this section
20 as the “Director”) shall evaluate the National Survey of
21 Family Growth conducted by the National Center for
22 Health Statistics of the Centers for Disease Control and
23 Prevention and consider making modifications to the sur-
24 vey questions used for such purposes.

1 (b) TOPICS.—The evaluation by the Director pursu-
2 ant to subsection shall include consideration of adding
3 questions related to—

4 (1) restorative reproductive health;

5 (2) reproductive health conditions and infer-
6 tility;

7 (3) restorative reproductive medicine availability
8 and utilization; and

9 (4) availability of, and training on, fertility
10 awareness-based methods.

11 (c) REPORT.—The Director shall submit to Congress
12 a report on the evaluation under subsection (a) not later
13 than 3 years after the date of enactment of this Act and
14 every 3 years thereafter.

15 **SEC. 8. INCLUDING ACCESS TO TITLE X AWARD FUNDS FOR**
16 **RESTORATIVE REPRODUCTIVE MEDICINE**
17 **GRANTEES.**

18 Section 1006 of the Public Health Service Act (42
19 U.S.C. 300a–4) is amended by adding at the end the fol-
20 lowing:

21 “(e)(1) Notwithstanding any other requirements re-
22 lating to the experience required for an applicant to qual-
23 ify for a grant or contract under this title, an entity shall
24 be deemed eligible for a grant or contract under this title
25 on the basis of being primarily engaged in providing re-

1 storative reproductive medicine, or providing training and
 2 education for medical students and professionals in restor-
 3 ative reproductive medicine, provided that such entity is
 4 otherwise eligible for the grant or contract.

5 “(2) In this subsection, the term ‘restorative repro-
 6 ductive medicine’ has the meaning given such term in sec-
 7 tion 3 of the RESTORE Act.”.

8 **SEC. 9. ADVANCING EDUCATION ON REPRODUCTIVE**
 9 **HEALTH CONDITIONS AND WOMEN’S NAT-**
 10 **URAL CYCLE.**

11 (a) **EXPANDING GRANT ACCESS AND APPLICA-**
 12 **TION.**—The Deputy Assistant Secretary for Population
 13 Affairs of the Department of Health and Human Services
 14 (referred to in this section as the “Deputy Assistant Sec-
 15 retary”) shall develop, within the existing Teen Pregnancy
 16 Prevention program, access to, and advertisement for, ap-
 17 plicants for grants under such program that specialize in
 18 restorative reproductive medicine, restorative reproductive
 19 health, and fertility awareness-based methods. To be eligi-
 20 ble to receive an award under this subsection, an entity
 21 shall be primarily engaged in services or education relating
 22 to restorative reproductive medicine, restorative reproduc-
 23 tive health, or fertility awareness-based methods.

24 (b) **REPORT.**—Not later than 18 months after the
 25 date of enactment of this Act, the Deputy Assistant Sec-

1 retary shall submit to Congress and make publicly avail-
2 able on the website of the Office of Population Affairs a
3 report on recipients of grants under the Teen Pregnancy
4 Prevention program and the services, education, and
5 training provided by such recipients.

6 **SEC. 10. ADVANCING RESTORATIVE REPRODUCTIVE MEDI-**
7 **CINE AND FERTILITY AWARENESS-BASED**
8 **METHODS TRAINING UNDER THE REPRODUC-**
9 **TIVE HEALTH NATIONAL TRAINING CENTER.**

10 (a) IN GENERAL.—The Assistant Secretary for
11 Health of the Department of Health and Human Services
12 (referred to in this section as the “Assistant Secretary”)
13 shall coordinate with the Office of Population Affairs and
14 the Office on Women’s Health to review, revise, and in-
15 struct the staff of the Reproductive Health National
16 Training Center on reproductive health conditions, restor-
17 ative reproductive medicine, restorative reproductive
18 health, and fertility awareness-based methods.

19 (b) TRAINING.—Beginning not later than 2 years
20 after the date of enactment of this Act, as a condition
21 for receipt of a grant or contract under title X of the Pub-
22 lic Health Service Act (42 U.S.C. 300 et seq.), the staff
23 of the Reproductive Health National Training Center shall
24 provide training to staff working in other entities receiving
25 grants or contracts under title X of the Public Health

1 Service Act (42 U.S.C. 300 et seq.) about reproductive
2 health conditions, restorative reproductive medicine, re-
3 storative reproductive health, and fertility awareness-
4 based methods, which may include providing toolkits and
5 other information, including online, about peer learning
6 opportunities, NaProTechnology educational fellowships,
7 fertility education and medical management, short videos
8 on reproductive health conditions and restorative repro-
9 ductive medicine, and contract medical professional semi-
10 nars and training.

11 **SEC. 11. EXPANDING RESEARCH ON REPRODUCTIVE**
12 **HEALTH CONDITIONS, FERTILITY AWARE-**
13 **NESS-BASED METHODS, AND INFERTILITY.**

14 (a) IN GENERAL.—The Secretary of Health and
15 Human Services (referred to in this section as the “Sec-
16 retary”), in coordination with the Assistant Secretary for
17 Health, the Director of the Agency for Healthcare Re-
18 search and Quality, the Director of the Advanced Re-
19 search Projects Agency for Health, the Director of the
20 Centers for Disease and Control, the Director of the Na-
21 tional Institutes for Health, and the heads of other agen-
22 cies and offices of the Department of Health and Human
23 Services that are conducting research on reproductive
24 health conditions, infertility, and maternal health, shall

1 expand and coordinate programs to conduct and support
2 research on reproductive health conditions.

3 (b) TOPICS.—The research directed by the Secretary
4 pursuant to subsection (a) may include research on—

5 (1) the causes of reproductive health conditions,
6 especially endometriosis, adenomyosis, uterine
7 fibroids, and polycystic ovary syndrome;

8 (2) ways to diagnose reproductive health condi-
9 tions;

10 (3) restorative reproductive medicine and new
11 treatment options for reproductive health conditions;

12 (4) endocrine disrupting chemicals in endo-
13 metriosis, the relationship of endometriosis and can-
14 cer, prenatal and epigenetic influences on the risk
15 for endometriosis;

16 (5) premenstrual syndrome, hormone dysfunc-
17 tion, ovulation defects, abnormal uterine bleeding,
18 adhesion prevention, tubal corrective surgery, and
19 preconception and pregnancy health;

20 (6) the growth and progression of reproductive
21 health conditions and recurrence post-surgical proce-
22 dures;

23 (7) the increasing prevalence of sexually trans-
24 mitted infections and related effects on fertility in
25 men and women;

1 (8) male mechanisms of infertility, including
2 low sperm count; and

3 (9) the effectiveness of restorative reproductive
4 medicine to achieve pregnancy.

5 (c) REPORT.—Not later than 2 years after the date
6 of enactment of this Act, the Secretary shall make an on-
7 going report on the research publicly available on the
8 website of the Department of Health and Human Services.

9 **SEC. 12. SEVERABILITY.**

10 If any provision of this Act, or the application of such
11 provision to any person, entity, government, or cir-
12 cumstance, is held to be unconstitutional, the remainder
13 of this Act, or the application of such provision to all other
14 persons, entities, governments, or circumstances, shall not
15 be affected thereby.

○