A BILL

To expand and promote research and data collection on reproductive health conditions, which are the leading causes of infertility, and provide training opportunities for medical professionals to learn how to diagnose and treat reproductive health conditions and for other purposes.

Section 1. SHORT TITLE

This Act may be cited as the "Empowering Women's Reproductive Health Act"

Section 2. FINDINGS

Congress finds the following:

- 1. There is a growing interest among women in proactively assessing their overall health and understanding how factors such as their age and medical history contribute to their reproductive health and fertility.
- 2. Women are worthy of the highest standard of medical care, including the opportunity to assess, understand, and improve their reproductive health. Unfortunately, many women do not receive adequate information about their reproductive health and access to restorative reproductive medicine.
- 3. Reproductive health conditions are the leading cause of infertility, affecting 11% of women and 9% of men in the United States.
- 4. Research shows that male and/or female infertility is typically due to four or more conditions or factors.
- 5. There is a gap in research and care for female reproductive health conditions, which affect a majority of women struggling with "unexplained infertility."
- 6. Restorative reproductive medicine aims to examine how a woman's reproductive functions and cycle interact with the rest of the female body.
- 7. Restorative reproductive medicine can eliminate barriers to successful conception, pregnancy, and birth. It can also address some causes of recurrent miscarriages.
- 8. Restorative reproductive medicine alleviates other difficult symptoms associated with reproductive health conditions, including but not limited to painful periods, painful flareups, bloating, inflammation, heavy periods, irregular periods, nerve pain, bowel symptoms, pain during sexual intercourse, and back pain.
- 9. *In vitro* fertilization and other assisted reproductive technologies are not under threat at the federal level or in any state, district, or federal territory.

Section 3. DEFINITIONS

In this Act:

- 1. Infertility—The term "infertility" means a symptom of an underlying disease or condition within a person's body that makes it difficult or impossible to successfully conceive and carry a live child to term where it should otherwise be possible through intercourse with a person of the other sex. A diagnosis of infertility often occurs after 12 months of unprotected intercourse for women under 35 or after six months of targeted intercourse without the use of a chemical, barrier, or other contraceptive method for women 35 and older.
- Restorative Reproductive Medicine (RRM)—The term "restorative reproductive medicine" means any scientific approach to reproductive medicine that seeks to cooperate with or restore the normal physiology and anatomy of the human reproductive system. It does not employ methods that are inherently suppressive, circumventive, or destructive to the human body.
- 3. Restorative Reproductive Health—The term "restorative reproductive health" includes empowering women and men to know and understand their bodies and appreciate the importance of natural reproductive health to overall health and well-being, including through the use of body literacy programs that incorporate science-based charting methods, teacher lead reproductive health education, restorative reproductive medicine, Natural Procreative Technology, fertility awareness-based methods, and fertility education and medical management.
- 4. Assisted Reproductive Technology—The term "assisted reproductive technology" means any treatments or procedures that involve the handling of a human egg, sperm, and embryo outside of the body with the intent of facilitating a pregnancy, including artificial insemination, intrauterine insemination, in vitro fertilization, gamete intrafallopian fertilization, zygote intrafallopian fertilization, egg, embryo, and sperm cryopreservation, and egg or embryo donation.
- 5. Natural Procreative Technology (NaProTECHNOLOGY)—The term "Natural Procreative Technology" or "NaProTECHNOLOGY" means an approach to health care that monitors and maintains a woman's reproductive and gynecological health, including laparoscopic gynecologic surgery to reconstruct the uterus, fallopian tubes, ovaries, and other organ structures to eliminate endometriosis and other reproductive health conditions.
- 6. Reproductive Health Conditions—The term "reproductive health conditions" includes endometriosis, adenomyosis, polycystic ovary syndrome, uterine fibroids, blocked fallopian tubes, hormone imbalances, hyperprolactinemia, thyroid conditions, ovulation dysfunctions, and other health conditions that make it difficult or impossible to successfully conceive a child where conception should otherwise be possible.
 - a. Endometriosis–The term "endometriosis" means a disease where tissue resembling endometrial lining tissue grows outside of the uterus. The tissue often sticks to different organs, disfiguring them and, through scar tissue or adhesions, can make the organs stick to one another or to the pelvic walls. It has been found

in the abdominal organs, the bowel, the diaphragm, the lungs, the brain, and the eye. It is a progressive disease and has been compared to growing like cancer. Endometriosis is often diagnosed in stages, with Stage I as the mildest form and Stage IV as the most severe and widespread form. The average diagnosis delay for endometriosis is ten to twelve years. Endometriosis frequently goes undiagnosed, and women may suffer for years with painful periods, pelvic pain, or infertility. The cause of endometriosis is unknown.

- b. Adenomyosis–The term "adenomyosis" means a disease that occurs when endometrial tissue (tissue that would normally line the inside of the uterus, distinct from endometriosis tissue) grows down into the muscle layer of the uterus. Adenomyosis is different from but can exist concurrently with endometriosis. Adenomyosis may increase the risk of miscarriage and preterm labor and may contribute to infertility. The cause of adenomyosis is unknown.
- c. Polycystic ovary syndrome (PCOS)–The term "polycystic ovary syndrome" means a reproductive hormonal disorder that causes cysts to grow on the ovaries, usually as a result of hormonal imbalances. Polycystic ovary syndrome affects approximately 15 percent of women overall but is more common among women with infertility. It is more prevalent among women with obesity and insulin resistance. Women with polycystic ovary syndrome who are trying to achieve pregnancy are commonly prescribed oral ovulation medication and hormonal injections that stimulate ovulation. Effective diagnosis and treatment exist, and should be made available for all women. Accurate and timely diagnosis and treatment can correct underlying hormonal imbalances, critical for both long-term health improvements as well as for fertility outcomes.
- d. Uterine fibroids–The term "uterine fibroids" means muscular tumors that grow in the wall of the uterus. While not all women will experience symptoms associated with fibroids, if the tumors are large enough or embedded far enough in the uterine lining, they can lead to pain and heavy bleeding. Treatment for fibroids may be a hysteroscopic myomectomy, abdominal myomectomy, uterine fibroid embolization (UFE), or uterine artery embolization (UAE). Uterine fibroids can increase risks of preterm labor, pregnancy complications leading to a cesarean section, and placental abruption, among other risks. The cause of uterine fibroids is unknown.
- e. Blocked Fallopian Tubes–The term "blocked fallopian tubes" means a condition where the fallopian tubes are blocked by tubal spasm, scarring from inflammatory conditions, debris, tubal polyps, tubal ligation, prior ectopic pregnancy, pelvic adhesions, endometriosis, prior pelvic infection (pelvic inflammatory disease or "PID"). Approximately 1 in 4 women with infertility have a tubal blockage. This condition makes achieving pregnancy difficult, if not impossible. Treatments for a

blockage include fallopian tube recanalization, tubo-tubal anastomosis (tubal ligation reversal), or neosalpingostomy/fimbrioplasty.

- 7. Fertility Awareness-Based Methods (FABMs)—The term "fertility awareness-based methods" means modern, evidence-based methods of tracking the menstrual cycle through observable biological signs in a woman, such as body temperature, cervical fluid, and hormone production in the reproductive system, including luteinizing hormone (LH) and estrogen. Such methods include Fertility Education and Medical Management, the sympto thermal method, the Marquette method, the Creighton method, and the Billings ovulation method.
- 8. Fertility Education and Medical Management (FEMM)—The term "fertility education and medical management" means the program developed in collaboration with the Reproductive Health Research Institute for medical research, protocols, and medical training for health care professionals in order to enable the clinical application of important research advances in reproductive endocrinology, by providing education for women about their bodies and hormonal health and medical support, as appropriate.

Section 4. RULES OF CONSTRUCTION

1. RELIGIOUS AND CONSCIENCE PROTECTIONS.–Nothing in this act shall require hospitals, individuals, employees, grantees, contractors, or entities to violate their consciences or religious beliefs by requiring or holding them liable for refusing to provide any health care reference in this act.

Section 5. IMPLEMENTING DATA COLLECTION ON THE STANDARD OF CARE FOR THE DIAGNOSIS OF INFERTILITY

- 1. DATA COLLECTION.—The Assistant Secretary for Health (in this section referred to as the "Assistant Secretary") shall implement data collection and produce a report every three years on the standard of care for women with infertility diagnoses.
- 2. TOPICS.-In carrying out the data collection under section (1), the Assistant Secretary must
 - a. collect and assess data related to restorative reproductive medicine prior to referral for or use of assisted reproductive technology;
 - i. Restorative reproductive medicine may include ultrasounds, blood tests, hormone panels, laparoscopic and exploratory surgeries, examining the woman's overall health and lifestyle, eliminating environmental endocrine disruptors, and assessing her partner's health and fertility;
 - b. collect and assess data related to access to information and training for fertility awareness-based methods;
 - c. assess group health plans or issuers of group or individual health insurance coverage of the treatments, tests, and training under subsections (2a) and (2b);

- 3. PRIVACY REQUIREMENTS—In carrying out the data collection under section (1), the Assistant Secretary shall ensure that the privacy and confidentiality of individual patients are protected in a manner consistent with relevant privacy and confidentiality laws.
- 4. REPORT.—No later than two years after the date of enactment of this Act, the Assistant Secretary shall submit to Congress and make publicly available on the website of the Department of Health and Human Services a report on the data collection carried out under this section.

Section 6. IMPLEMENTING DATA COLLECTION ON THE STANDARD OF CARE FOR WOMEN SEEKING A REPRODUCTIVE HEALTH CONDITION DIAGNOSIS

- 1. DATA COLLECTION.—The Assistant Secretary for Health (in this section referred to as the "Assistant Secretary") shall implement data collection and produce a report every three years on the standard of care for women seeking reproductive health condition diagnoses.
- 2. TOPICS.-In carrying out the data collection under section (1), the Assistant Secretary must
 - a. collect and assess data related to access to restorative reproductive medicine and restorative reproductive health, including access to medical professionals trained in NaProTechnology and FEMM;
 - b. collect and assess data related to access to information and training on fertility awareness-based methods;
 - c. assess group health plans or issuers of group or individual health insurance coverage of the treatments, tests, and training under subsections (2a) and (2b);
- 3. PRIVACY REQUIREMENTS—In carrying out the data collection under section (1), the Assistant Secretary shall ensure that the privacy and confidentiality of individual patients are protected in a manner consistent with relevant privacy and confidentiality laws.
- 4. REPORT.—No later than two years after the date of enactment of this Act, the Assistant Secretary shall submit to Congress and make publicly available on the website of the Department of Health and Human Services a report on the data collection carried out under this section.

Section 7. EXPANDING THE NATIONAL SURVEY OF FAMILY GROWTH TO INCLUDE REPRODUCTIVE HEALTH CONDITIONS, RESTORATIVE REPRODUCTIVE MEDICINE, AND FERTILITY AWARENESS-BASED METHODS.

- 1. IN GENERAL.-The Director of the Centers for Disease Control and Prevention (in this section referred to as the "Director") shall evaluate the National Survey of Family Growth data collection and explore modifications to the survey questions.
- 2. TOPICS.-In carrying out the survey under section (1), the Director must
 - a. evaluate and consider adding questions related to women's overall reproductive health;

- b. evaluate and consider adding questions related to reproductive health conditions and infertility;
- c. evaluate and consider adding questions related to restorative reproductive medicine availability and utilization;
- d. evaluate and consider adding questions related to fertility awareness-based methods availability and training.
- 3. REPORT.–The results of the survey report shall be submitted to Congress and made publicly available every three years, pending the availability of funding.

Section 8. INCLUDING ACCESS TO TITLE X AWARD FUNDS FOR RESTORATIVE REPRODUCTIVE MEDICINE GRANTEES

1. Section 1006 of the Public Health Service Act (42 U.S.C. 300a–4) section a is amended by adding the following:

(a)(1) Notwithstanding any other provision of law, section (a) of this act may not exclude entities that provide restorative reproductive medicine, as defined in the Empowering Women's Reproductive Health Act, from receiving the grants and contracts provided to other entities described in this act.

(a)(2) Notwithstanding any other provision of law, section (a) of this act may not exclude entities that provide training and education for medical students and professionals in restorative reproductive medicine, as defined in the Empowering Women's Reproductive Health Act, from receiving the grants and contracts provided to other entities described in this act.

Section 9. ADVANCING EDUCATION ON REPRODUCTIVE HEALTH CONDITIONS AND WOMEN'S NATURAL CYCLE

- 1. EXPANDING GRANT ACCESS AND APPLICATION-The Deputy Assistant Secretary of the Office of Population Affairs (in this section referred to as the "Deputy Assistant Secretary") shall develop within the already existing Teen Pregnancy Prevention Program (TPP) access to and advertisement for grantees that specialize in restorative reproductive medicine, restorative reproductive health, and fertility awareness-based methods.
- 2. REPORT.—No later than 18 months after the date of enactment of this Act, the Deputy Assistant Secretary shall submit to Congress and make publicly available on the website of the Office of Population Affairs a report on the TPP grantees and their provided services, education, and training.

Section 10. ADVANCING RESTORATIVE REPRODUCTIVE MEDICINE AND FERTILITY AWARENESS-BASED METHODS TRAINING UNDER THE REPRODUCTIVE HEALTH NATIONAL TRAINING CENTER

- 1. IN GENERAL.-The Assistant Secretary for Health (in this section referred to as the "Assistant Secretary") shall oversee that the Office of Population Affairs and the Office on Women's Health to review, revise, and instruct the Reproductive Health National Training Center (RHNTC) staff on reproductive health conditions, restorative reproductive medicine, restorative reproductive health, and fertility awareness-based methods.
- 2. TRAINING-The RHNTC staff must, within two years of the enactment of this Act, provide training to staff working in the Title X Family Planning Program and Teen Pregnancy Prevention Program about reproductive health conditions, restorative reproductive medicine, restorative reproductive health, and fertility awareness-based methods.
 - a. This training may include RRM, FEMM, and FABMs toolkits, peer learning opportunities, NaProTechnology educational fellowships, FEMM and FABMs education, short videos on reproductive health conditions and restorative reproductive medicine, and contract medical professional seminars and training on RRM, FEMM, and FABMs.

Section 11. EXPANDING RESEARCH ON REPRODUCTIVE HEALTH CONDITIONS, FERTILITY AWARENESS-BASED METHODS, AND INFERTILITY.

- 1. IN GENERAL.—The Secretary of Health and Human Services (referred to in this Act as the "Secretary") shall expand and coordinate programs to conduct and support research on reproductive health conditions.
- 2. RESEARCH.-The Secretary shall coordinate this research initiative with the Office of the Assistant Secretary for Health, the Agency for Healthcare Research and Quality, the Advanced Research Projects Agency for Health, the Centers for Disease and Control, the National Institutes for Health, and any other subagency already conducting research on reproductive health conditions, infertility, and maternal health.
- 3. TOPICS.-In carrying out the survey under section (1), the Secretary may
 - a. direct research on the causes of reproductive health conditions, especially endometriosis, adenomyosis, uterine fibroids, and polycystic ovary syndrome;
 - b. direct research on ways to diagnose reproductive health conditions;
 - c. direct research on restorative reproductive medicine and new treatment options for reproductive health conditions;
 - d. direct targeted research on endocrine disrupting chemicals in endometriosis, the relationship of endometriosis and cancer, prenatal and epigenetic influences on the risk for endometriosis;
 - e. direct research on the growth and progression of reproductive health conditions and recurrence post-surgical procedures;
 - f. direct research on male mechanisms of infertility.

- g. direct research on the effectiveness of fertility awareness-based methods to achieve pregnancy.
- 4. REPORT.–No later than 24 months after the date of enactment of this Act, the Secretary shall make an ongoing report on the research publicly available on the Department of Health and Human Services website.

Section 12. SEVERABILITY.

1. If any provision of this Act, or the application of such provision to any person, entity, government, or circumstance, is held to be unconstitutional, the remainder of this Act, or the application of such provision to all other persons, entities, governments, or circumstances, shall not be affected thereby.