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(Original Signature of Member)

117TH CONGRESS
1ST SESSION

H. R. _____

To require more accurate reporting of abortion drug prescribing and related adverse events, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mrs. WALORSKI introduced the following bill; which was referred to the Committee on _____

A BILL

To require more accurate reporting of abortion drug prescribing and related adverse events, 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 “Safeguarding Women’s
5 and Children’s Health Act of 2022”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds the following:

1 (1) Many data limitations affect the accuracy of
2 statistics related to chemical abortions in the United
3 States, and there is no central database tracking
4 this information.

5 (2) States may voluntarily choose to share abor-
6 tion data with the Centers for Disease Control and
7 Prevention (CDC), but the Guttmacher Institute,
8 which directly surveys abortion providers, consist-
9 ently documents 30 to 40 percent more abortions
10 than the CDC.

11 (3) Some States with high volumes of abortion,
12 such as California, do not report to the CDC.

13 (4) Only 28 States require abortion providers to
14 report complications, but there is rarely an enforced
15 penalty for noncompliance. Only 12 States require
16 other physicians, coroners, or emergency rooms to
17 report complications or deaths for investigation, and
18 frequently these facilities and physicians are un-
19 aware of these reporting requirements.

20 (5) These data problems are a significant limi-
21 tation to United States studies on abortion complica-
22 tions.

23 (6) Women experiencing complications will
24 often present to an emergency room rather than re-
25 turn to the abortion provider, and researchers fre-

1 quently ignore the difficulty in obtaining accurate
2 International Classification of Diseases coding in
3 emergency rooms due to search engine failure to dis-
4 cover induced abortion codes, which leads to
5 miscoding and frequently attributing induced abor-
6 tion complications to spontaneous abortions.

7 (7) When compared to surgical abortions, chem-
8 ical abortions are over 50 percent more likely to re-
9 sult in an abortion-related visit to an emergency
10 room, and by 2015, 60 percent of chemical abortion-
11 related emergency room visits were incorrectly coded
12 as miscarriages.

13 (8) Better quality, international records-link-
14 ages studies, and meta-analyses document far higher
15 rates of complications and mortality from abortion,
16 casting doubt on the validity of the reported data by
17 which United States public health decisions are
18 made.

19 (9) Independent systematic analysis of adverse
20 event reports submitted to the Food and Drug Ad-
21 ministration (FDA) between 2000 and 2019 re-
22 vealed approximately 3,000 United States adverse
23 events out of an expected 185,000 adverse events
24 based on the known and published complication rate
25 after mifepristone misoprostol abortions. Thus, the

1 Adverse Event Reporting System of the FDA cap-
2 tured only 1.7 percent of the actual adverse events
3 occurring in United States women, the majority of
4 which occurred prior to 2016 when mifepristone pre-
5 scribers were required to report adverse events as
6 part of the risk evaluation and mitigation strategy.

7 (10) In 2016, the FDA relaxed the gestational
8 age dispensing from a limitation of 7 weeks gesta-
9 tion to a limitation of 10 weeks gestation, and at the
10 same time the FDA no longer required mifepristone
11 prescribers to report adverse events other than
12 death. These simultaneous changes ensured that
13 there would be no way to capture the increased ad-
14 verse events resulting from the relaxation of the ges-
15 tational age requirements.

16 (11) In order to fulfil the statutory requirement
17 of the FDA to oversee and evaluate the safety of
18 mifepristone use as an abortifacient, substantial
19 changes in the adverse event reporting for
20 mifepristone must be implemented to obtain an ac-
21 curate evaluation of the impact of mifepristone-re-
22 lated adverse events on United States women.

1 **SEC. 3. ACCURATE REPORTING ON CHEMICAL ABORTION**
2 **AND RELATED ADVERSE EVENTS.**

3 (a) REPORTING REQUIREMENTS.—The Secretary of
4 Health and Human Services, acting through the Commis-
5 sioner of Food and Drugs, shall require any abortion drug,
6 including any abortion drug approved by the Food and
7 Drug Administration before the date of enactment of this
8 Act, to have a risk evaluation and mitigation strategy re-
9 quiring that—

10 (1) within 15 days of becoming aware of any
11 death or other adverse event in a patient associated
12 with the use of such abortion drug, a health care
13 provider shall—

14 (A) report such death or adverse event to
15 the Food and Drug Administration and to the
16 manufacturer of such abortion drug; and

17 (B) identify in such reporting the patient
18 by a nonidentifiable reference and the serial
19 number from each package of such abortion
20 drug if available; and

21 (2) a health care practitioner who prescribes,
22 dispenses, or administers such abortion drug shall—

23 (A) within 15 days of such prescribing,
24 dispensing, or administering, report the action
25 to the Food and Drug Administration and the

1 Centers for Disease Control and Prevention;
2 and

3 (B) exclude from such reporting any indi-
4 vidually identifiable patient information.

5 (b) PORTALS.—The Secretary of Health and Human
6 Services, acting through the Commissioner of Food and
7 Drugs, shall—

8 (1) establish and maintain an online portal that
9 allows health care practitioners to easily, confiden-
10 tially, and securely report to the Food and Drug Ad-
11 ministration and the Centers for Disease Control
12 and Prevention by means of online transmission the
13 information required by subsection (a) to be re-
14 ported; and

15 (2) establish and maintain an online portal that
16 allows patients to easily, confidentially, and securely
17 self-report to the Food and Drug Administration
18 and the Centers for Disease Control and Prevention
19 by means of online transmission any adverse events
20 the patients have experienced that are associated
21 with use of an abortion drug.

22 (c) DEFINITIONS.—In this section:

23 (1) The term “abortion drug” means any drug,
24 substance, or combination of drugs or substances

1 that is intended for use or that is in fact used (irre-
2 spective of how the product is labeled)—

3 (A) to intentionally kill the unborn child of
4 a woman known to be pregnant; or

5 (B) to intentionally terminate the preg-
6 nancy of a woman known to be pregnant, with
7 an intention other than—

8 (i) to produce a live birth;

9 (ii) to remove a dead unborn child; or

10 (iii) to treat an ectopic or molar preg-
11 nancy.

12 (2) The term “adverse event” means any unto-
13 ward medical occurrence associated with the use of
14 a drug in humans, whether or not considered drug-
15 related.

16 (3) The term “unborn child” means an indi-
17 vidual organism of the species homo sapiens, begin-
18 ning at fertilization, until the point of being born
19 alive as defined in section 8(b) of title 1, United
20 States Code.

21 **SEC. 4. IMPROVED REPORTING OF DATA RELATED TO**
22 **CHEMICAL ABORTIONS.**

23 The Public Health Service Act is amended by insert-
24 ing after section 317U of such Act (42 U.S.C. 247b–23)
25 the following:

1 **“SEC. 317V. IMPROVED REPORTING OF DATA RELATED TO**
2 **CHEMICAL ABORTIONS.**

3 “(a) IN GENERAL.—The Secretary, acting through
4 the Director of the Centers for Disease Control and Pre-
5 vention, shall—

6 “(1) collect and aggregate in a standardized
7 format information that is reported pursuant to sec-
8 tion 3 of the Safeguarding Women’s and Children’s
9 Health Act of 2022 with respect to abortion drugs;

10 “(2) make such information available in accord-
11 ance with section 552 of title 5, United States Code;
12 and

13 “(3) annually publish—

14 “(A) the number of abortion drugs pre-
15 scribed in the United States;

16 “(B) the number of abortion drugs that
17 are shipped directly to prescribers and to pa-
18 tients;

19 “(C) the total number of deaths that oc-
20 curred within 120 days of ingestion of an abor-
21 tion drug, regardless of causal attribution, and
22 the cause of death;

23 “(D) the total number of serious adverse
24 events that occurred within 120 days of inges-
25 tion of an abortion drug;

1 “(E) the number of times each such seri-
2 ous adverse event occurred;

3 “(F) the total number of all adverse events
4 that occurred within 120 days of ingestion of
5 an abortion drug, stratified by the Common
6 Terminology for Coding Adverse Events (or any
7 successor publication) criteria for severity grad-
8 ing; and

9 “(G) the number of times abortion drug
10 ingestion resulted in an incomplete abortion.

11 “(b) TECHNICAL ASSISTANCE.—The Secretary shall
12 provide technical assistance to facilitate and improve the
13 reporting of data for purposes of this section.

14 “(c) ANNUAL REPORTING.—The Secretary shall—

15 “(1) annually publish a report on the data col-
16 lected and aggregated pursuant to subsection (a)(1);
17 and

18 “(2) post such report on the public website of
19 the Food and Drug Administration.

20 “(d) DEFINITIONS.—In this section:

21 “(1) The term ‘abortion drug’ means any drug,
22 substance, or combination of drugs or substances
23 that is intended for use or that is in fact used (irre-
24 spective of how the product is labeled)—

1 “(A) to intentionally kill the unborn child
2 of a woman known to be pregnant; or

3 “(B) to intentionally terminate the preg-
4 nancy of a woman known to be pregnant, with
5 an intention other than—

6 “(i) to produce a live birth;

7 “(ii) to remove a dead unborn child;

8 or

9 “(iii) to treat an ectopic or molar
10 pregnancy.

11 “(2) The term ‘adverse event’ means any unto-
12 ward medical occurrence associated with the use of
13 a drug in humans, whether or not considered drug-
14 related.

15 “(3) The term ‘serious adverse event’ means an
16 adverse event that meets Common Terminology for
17 Coding Adverse Events criteria (or any successor
18 publication) for level 3 or above.

19 “(4) The term ‘unborn child’ means an indi-
20 vidual organism of the species homo sapiens, begin-
21 ning at fertilization, until the point of being born
22 alive as defined in section 8(b) of title 1, United
23 States Code.”.