I

117TH CONGRESS
2D SESSION

H. R. 6702

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

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 9, 2022

Mrs. WALORSKI (for herself, Mr. MCKINLEY, Mr. LONG, Mr. DUNCAN, Mr. BANKS, Mr. MOONEY, Mr. LAMBORN, Mr. CURTIS, Mr. HUDSON, Mr. ELLZEY, Mr. BABIN, Mrs. MILLER-MEEKS, Ms. FOXX, Mr. BURCHETT, Mr. BURGESS, Mr. FEENSTRA, Mr. JOYCE of Pennsylvania, Mr. LAMALFA, Mr. C. SCOTT FRANKLIN of Florida, Mrs. FISCHBACH, and Mr. LUETKEMEYER) introduced the following bill; which was referred to the Committee on Energy and Commerce

---

A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Safeguarding Women's and Children's Health Act of 2022''.

SEC. 2. FINDINGS.

The Congress finds the following:

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

(2) States may voluntarily choose to share abortion data with the Centers for Disease Control and Prevention (CDC), but the Guttmacher Institute, which directly surveys abortion providers, consistently documents 30 to 40 percent more abortions than the CDC.

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

(4) Only 28 States require abortion providers to report complications, but there is rarely an enforced penalty for noncompliance. Only 12 States require other physicians, coroners, or emergency rooms to report complications or deaths for investigation, and frequently these facilities and physicians are unaware of these reporting requirements.

(5) These data problems are a significant limitation to United States studies on abortion complications.

(6) Women experiencing complications will often present to an emergency room rather than return to the abortion provider, and researchers fre-

quently ignore the difficulty in obtaining accurate International Classification of Diseases coding in emergency rooms due to search engine failure to discover induced abortion codes, which leads to miscoding and frequently attributing induced abortion complications to spontaneous abortions.

(7) When compared to surgical abortions, chemical abortions are over 50 percent more likely to result in an abortion-related visit to an emergency room, and by 2015, 60 percent of chemical abortion-related emergency room visits were incorrectly coded as miscarriages.

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

(9) Independent systematic analysis of adverse event reports submitted to the Food and Drug Administration (FDA) between 2000 and 2019 revealed approximately 3,000 United States adverse events out of an expected 185,000 adverse events based on the known and published complication rate after mifepristone misoprostol abortions. Thus, the

Adverse Event Reporting System of the FDA captured only 1.7 percent of the actual adverse events occurring in United States women, the majority of which occurred prior to 2016 when mifepristone prescribers were required to report adverse events as part of the risk evaluation and mitigation strategy.

(10) In 2016, the FDA relaxed the gestational age dispensing from a limitation of 7 weeks gestation to a limitation of 10 weeks gestation, and at the same time the FDA no longer required mifepristone prescribers to report adverse events other than death. These simultaneous changes ensured that there would be no way to capture the increased adverse events resulting from the relaxation of the gestational age requirements.

(11) In order to fulfil the statutory requirement of the FDA to oversee and evaluate the safety of mifepristone use as an abortifacient, substantial changes in the adverse event reporting for mifepristone must be implemented to obtain an accurate evaluation of the impact of mifepristone-related adverse events on United States women.

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

(a) REPORTING REQUIREMENTS.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall require any abortion drug, including any abortion drug approved by the Food and Drug Administration before the date of enactment of this Act, to have a risk evaluation and mitigation strategy requiring that—

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

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

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

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

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

Centers for Disease Control and Prevention; and

(B) exclude from such reporting any individually identifiable patient information.

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

(1) establish and maintain an online portal that allows health care practitioners to easily, confidentially, and securely report to the Food and Drug Administration and the Centers for Disease Control and Prevention by means of online transmission the information required by subsection (a) to be reported; and

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

(c) DEFINITIONS.—In this section:

(1) The term ''abortion drug'' means any drug, substance, or combination of drugs or substances

that is intended for use or that is in fact used (irrespective of how the product is labeled)—

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

(B) to intentionally terminate the pregnancy of a woman known to be pregnant, with an intention other than—

(i) to produce a live birth;

(ii) to remove a dead unborn child; or

(iii) to treat an ectopic or molar pregnancy.

(2) The term ''adverse event'' means any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug-related.

(3) The term ''unborn child'' means an individual organism of the species homo sapiens, beginning at fertilization, until the point of being born alive as defined in section 8(b) of title 1, United States Code.

SEC. 4. IMPROVED REPORTING OF DATA RELATED TO CHEMICAL ABORTIONS.

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

"SEC. 317V. IMPROVED REPORTING OF DATA RELATED TO CHEMICAL ABORTIONS.

"(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall—

"(1) collect and aggregate in a standardized format information that is reported pursuant to section 3 of the Safeguarding Women's and Children's Health Act of 2022 with respect to abortion drugs;

"(2) make such information available in accordance with section 552 of title 5, United States Code; and

"(3) annually publish—

"(A) the number of abortion drugs prescribed in the United States;

"(B) the number of abortion drugs that are shipped directly to prescribers and to patients;

"(C) the total number of deaths that occurred within 120 days of ingestion of an abortion drug, regardless of causal attribution, and the cause of death;

"(D) the total number of serious adverse events that occurred within 120 days of ingestion of an abortion drug;

''(E) the number of times each such serious adverse event occurred;

''(F) the total number of all adverse events that occurred within 120 days of ingestion of an abortion drug, stratified by the Common Terminology for Coding Adverse Events (or any successor publication) criteria for severity grading; and

''(G) the number of times abortion drug ingestion resulted in an incomplete abortion.

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

''(c) ANNUAL REPORTING.—The Secretary shall—

''(1) annually publish a report on the data collected and aggregated pursuant to subsection (a)(1); and

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

''(d) DEFINITIONS.—In this section:

''(1) The term 'abortion drug' means any drug, substance, or combination of drugs or substances that is intended for use or that is in fact used (irrespective of how the product is labeled)—

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

"(B) to intentionally terminate the pregnancy of a woman known to be pregnant, with an intention other than—

"(i) to produce a live birth;

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

"(iii) to treat an ectopic or molar pregnancy.

"(2) The term 'adverse event' means any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug-related.

"(3) The term 'serious adverse event' means an adverse event that meets Common Terminology for Coding Adverse Events criteria (or any successor publication) for level 3 or above.

"(4) The term 'unborn child' means an individual organism of the species homo sapiens, beginning at fertilization, until the point of being born alive as defined in section 8(b) of title 1, United States Code.".

○