

116TH CONGRESS
1ST SESSION

H. R. 4399

To amend the Federal Food, Drug, and Cosmetic Act to prohibit the approval of new abortion drugs, to prohibit investigational use exemptions for abortion drugs, and to impose additional regulatory requirements with respect to previously approved abortion drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 19, 2019

Mr. LATTA (for himself, Mrs. WAGNER, Mr. NORMAN, Mr. OLSON, Mr. LAMBORN, Mr. MEADOWS, Mr. ALLEN, Mr. WILLIAMS, Mr. SMITH of New Jersey, Mr. WEBER of Texas, Mr. WATKINS, Mr. GIANFORTE, Mr. CHABOT, Mr. BABIN, Mr. RATCLIFFE, Mr. LOUDERMILK, Mr. RUTHERFORD, Mr. LAMALFA, Mr. FLORES, Mr. KEVIN HERN of Oklahoma, Mr. ABRAHAM, Mr. HARRIS, Mrs. HARTZLER, Mr. ESTES, Mr. GIBBS, Mr. GROTHMAN, Mr. WITTMAN, Ms. FOXX of North Carolina, Mr. WALBERG, and Mr. HIGGINS of Louisiana) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to prohibit the approval of new abortion drugs, to prohibit investigational use exemptions for abortion drugs, and to impose additional regulatory requirements with respect to previously approved abortion drugs, 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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Support And Value
3 Expectant Moms and Babies Act of 2019” or the “SAVE
4 Moms and Babies Act of 2019”.

5 **SEC. 2. ABORTION DRUGS PROHIBITED.**

6 (a) IN GENERAL.—Section 505 of the Federal Food,
7 Drug, and Cosmetic Act (21 U.S.C. 355) is amended by
8 adding at the end the following:

9 “(z) ABORTION DRUGS.—

10 “(1) PROHIBITIONS.—The Secretary shall not
11 approve—

12 “(A) any application submitted under sub-
13 section (b) or (j) for marketing an abortion
14 drug; or

15 “(B) grant an investigational use exemp-
16 tion under subsection (i) for—

17 “(i) an abortion drug; or

18 “(ii) any investigation in which the
19 human embryo or human fetus of a woman
20 known to be pregnant is knowingly de-
21 stroyed.

22 “(2) PREVIOUSLY APPROVED ABORTION
23 DRUGS.—If an approval described in paragraph (1)
24 is in effect for an abortion drug as of the date of
25 enactment of the Support And Value Expectant
26 Moms and Babies Act of 2019, the Secretary shall—

1 “(A) not approve any labeling change—

2 “(i) to approve the use of such abor-
3 tion drug after 70 days gestation; or

4 “(ii) to approve the dispensing of such
5 abortion drug by any means other than in-
6 person administration by the prescribing
7 health care practitioner;

8 “(B) treat such abortion drug as subject to
9 section 503(b)(1); and

10 “(C) require such abortion drug to be sub-
11 ject to a risk evaluation and mitigation strategy
12 under section 505–1 that at a minimum—

13 “(i) requires health care practitioners
14 who prescribe such abortion drug—

15 “(I) to be certified in accordance
16 with the strategy; and

17 “(II) to not be acting in their ca-
18 pacity as a pharmacist;

19 “(ii) as part of the certification proc-
20 ess referred to in clause (i), requires such
21 practitioners—

22 “(I) to have the ability to assess
23 the duration of pregnancy accurately;

24 “(II) to have the ability to diag-
25 nose ectopic pregnancies;

1 “(III) to have the ability to pro-
2 vide surgical intervention in cases of
3 incomplete abortion or severe bleed-
4 ing;

5 “(IV) to have the ability to en-
6 sure patient access to medical facili-
7 ties equipped to provide blood trans-
8 fusions and resuscitation, if necessary;
9 and

10 “(V) to report any deaths or
11 other adverse events associated with
12 the use of such abortion drug to the
13 Food and Drug Administration and to
14 the manufacturer of such abortion
15 drug, identifying the patient by a non-
16 identifiable reference and the serial
17 number from each package of such
18 abortion drug;

19 “(iii) limits the dispensing of such
20 abortion drug to patients—

21 “(I) in a clinic, medical office, or
22 hospital by means of in-person admin-
23 istration by the prescribing health
24 care practitioner; and

1 “(II) not in pharmacies or any
2 setting other than the health care set-
3 tings described in subclause (I);

4 “(iv) requires the prescribing health
5 care practitioner to give to the patient doc-
6 umentation on any risk of serious com-
7 plications associated with use of such abor-
8 tion drug and receive acknowledgment of
9 such receipt from the patient;

10 “(v) requires all known adverse events
11 associated with such abortion drug to be
12 reported, excluding any individually identi-
13 fiable patient information, to the Food and
14 Drug Administration by the—

15 “(I) manufacturers of such abor-
16 tion drug; and

17 “(II) prescribers of such abortion
18 drug; and

19 “(vi) requires reporting of administra-
20 tion of the abortion drug as required by
21 State law, or in the absence of a State law
22 regarding such reporting, in the same
23 manner as a surgical abortion.

24 “(3) REPORTING ON ADVERSE EVENTS BY
25 OTHER HEALTH CARE PRACTITIONERS.—The Sec-

1 retary shall require all other health care practi-
2 tioners to report to the Food and Drug Administra-
3 tion any adverse events experienced by their patients
4 that are connected to use of an abortion drug, ex-
5 cluding any individually identifiable patient informa-
6 tion.

7 “(4) RULE OF CONSTRUCTION.—Nothing in
8 this section shall be construed to restrict the author-
9 ity of the Secretary, or of a State, to establish, im-
10 plement, and enforce requirements and restrictions
11 with respect to abortion drugs under provisions of
12 law other than this section that are in addition to
13 the requirements and restrictions under this section.

14 “(5) DEFINITIONS.—In this section:

15 “(A) The term ‘abortion drug’ means any
16 drug, substance, or combination of drugs or
17 substances that is intended for use or that is in
18 fact used (irrespective of how the product is la-
19 beled)—

20 “(i) to intentionally kill the unborn
21 child of a woman known to be pregnant; or

22 “(ii) to intentionally terminate the
23 pregnancy of a woman known to be preg-
24 nant, with an intention other than—

25 “(I) to produce a live birth; or

1 “(II) to remove a dead unborn
2 child.

3 “(B) The term ‘adverse event’ includes
4 each of the following:

5 “(i) A fatality.

6 “(ii) An ectopic pregnancy.

7 “(iii) A hospitalization.

8 “(iv) A blood loss requiring a trans-
9 fusion.

10 “(v) An infection, including endo-
11 metritis, pelvic inflammatory disease, and
12 pelvic infections with sepsis.

13 “(vi) A severe infection.

14 “(C) The term ‘gestation’ means the pe-
15 riod of days beginning on the first day of the
16 last menstrual period.

17 “(D) The term ‘health care practitioner’
18 means any individual who is licensed, reg-
19 istered, or otherwise permitted, by the United
20 States or the jurisdiction in which the indi-
21 vidual practices, to prescribe drugs subject to
22 section 503(b)(1).

23 “(E) The term ‘unborn child’ means an in-
24 dividual organism of the species *homo sapiens*,
25 beginning at fertilization, until the point of

1 being born alive as defined in section 8(b) of
2 title 1, United States Code.”.

3 (b) ONGOING INVESTIGATIONAL USE.—In the case of
4 any investigational use of a drug pursuant to an investiga-
5 tional use exemption under section 505(i) of the Federal
6 Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) that
7 was granted before the date of enactment of this Act, such
8 exemption is deemed to be rescinded as of the day that
9 is 3 years after the date of enactment of this Act if the
10 Secretary would be prohibited by section 505(z)(1)(B) of
11 the Federal Food, Drug, and Cosmetic Act, as added by
12 subsection (a), from granting such exemption as of such
13 day.

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