

118TH CONGRESS  
1ST SESSION

# H. R. 427

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.

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## IN THE HOUSE OF REPRESENTATIVES

JANUARY 20, 2023

Mr. LATA (for himself, Mrs. HARSHBARGER, Mr. ADERHOLT, Mr. RESCHENTHALER, Ms. LETLOW, Mr. FINSTAD, Mr. GROTHMAN, Mr. LUETKEMEYER, Mr. DUNN of Florida, Mr. BOST, Mr. BABIN, Mr. PALMER, Mr. WENSTRUP, Mr. ELLZEY, Mrs. MILLER of Illinois, Mr. SMITH of New Jersey, Mr. BANKS, Mr. FEENSTRA, Mr. PFLUGER, Mr. BIGGS, Mr. C. SCOTT FRANKLIN of Florida, Mr. WEBER of Texas, Mr. WALBERG, Mr. LAHOOD, Mr. JACKSON of Texas, Mr. MANN, Mr. BALDERSON, Mr. ROSE, Mr. GUEST, Mrs. BOEBERT, Mr. WALTZ, Mr. PERRY, and Mr. MCHENRY) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## 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 2023” or the “SAVE  
4 Moms and Babies Act of 2023”.

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) (as amended by  
8 Public Law 117–328) is amended by adding at the end  
9 the following:

10 “(aa) ABORTION DRUGS.—

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

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

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

18 “(i) an abortion drug; or

19 “(ii) any investigation in which the  
20 unborn child of a woman known to be  
21 pregnant is knowingly destroyed.

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 2023, 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 Federal Government, or of a State, to es-  
10      tablish, implement, and enforce requirements and re-  
11      strictions with respect to abortion drugs under provi-  
12      sions of law other than this section that are in addi-  
13      tion to the requirements and restrictions under this  
14      section.

15              “(5) DEFINITIONS.—In this section:

16                      “(A) The term ‘abortion drug’ means any  
17                      drug, substance, or combination of drugs or  
18                      substances that is intended for use or that is in  
19                      fact used (irrespective of how the product is la-  
20                      beled) to intentionally kill the unborn child of  
21                      a woman known to be pregnant, or to inten-  
22                      tionally terminate the pregnancy of a woman  
23                      known to be pregnant, with an intention other  
24                      than—

25                              “(i) to produce a live birth;

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

2 or

3 “(iii) to treat an ectopic pregnancy.

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

6 “(i) A fatality.

7 “(ii) An ectopic pregnancy.

8 “(iii) A hospitalization.

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

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

14 “(vi) A severe infection.

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

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

24 “(E) The term ‘unborn child’ means an in-  
25 dividual organism of the species homo sapiens,

1 beginning at fertilization, until the point of  
2 being born alive as defined in section 8(b) of  
3 title 1, United States Code.”.

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

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