

119TH CONGRESS
2D SESSION

S. 3697

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 SENATE OF THE UNITED STATES

JANUARY 27, 2026

Mrs. HYDE-SMITH (for herself, Mr. DAINES, Mr. RISCH, Mr. ROUNDS, Mr. WICKER, Mr. LANKFORD, Mr. MCCONNELL, Ms. LUMMIS, Mr. CRUZ, Mr. BANKS, Mr. MARSHALL, Mrs. BRITT, Mr. SCOTT of Florida, Mr. HAWLEY, Mr. CRAPO, Mr. BUDD, Mr. GRAHAM, Mr. CASSIDY, Mr. CORNYN, Ms. ERNST, Mr. LEE, Mr. CRAMER, Mr. RICKETTS, Mrs. FISCHER, Mr. KENNEDY, Mr. HOEVEN, Mr. YOUNG, Mr. HAGERTY, Mr. COTTON, Mr. MORAN, and Mrs. BLACKBURN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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 2026” or the “SAVE
4 Moms and Babies Act of 2026”.

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—

8 (1) by redesignating the second subsection (z),
9 as added by section 3601(a) of division FF of Public
10 Law 117–328, as subsection (aa); and

11 (2) by adding at the end the following:

12 “(bb) ABORTION DRUGS.—

13 “(1) PROHIBITIONS.—The Secretary shall not
14 approve—

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

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

20 “(i) an abortion drug; or

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

24 “(2) PREVIOUSLY APPROVED ABORTION
25 DRUGS.—If an approval described in paragraph (1)
26 is in effect for an abortion drug as of the date of

1 enactment of the Support And Value Expectant
2 Moms and Babies Act of 2026, the Secretary shall—

3 “(A) not approve any labeling change—

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

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

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

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

15 “(i) requires health care practitioners
16 who prescribe such abortion drug—

17 “(I) to be certified in accordance
18 with the strategy; and

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

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

24 “(I) to have the ability to assess
25 the duration of pregnancy accurately;

1 “(II) to have the ability to diag-
2 nose ectopic pregnancies;

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

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

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

21 “(iii) limits the dispensing of such
22 abortion drug to patients—

23 “(I) in a clinic, medical office, or
24 hospital by means of in-person admin-

1 istration by the prescribing health
2 care practitioner; and

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

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

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

17 “(I) manufacturers of such abor-
18 tion drug; and

19 “(II) prescribers of such abortion
20 drug; and

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

1 “(3) REPORTING ON ADVERSE EVENTS BY
 2 OTHER HEALTH CARE PRACTITIONERS.—The Sec-
 3 retary shall require all other health care practi-
 4 tioners to report to the Food and Drug Administra-
 5 tion any adverse events experienced by their patients
 6 that are connected to use of an abortion drug, ex-
 7 cluding any individually identifiable patient informa-
 8 tion.

9 “(4) RULE OF CONSTRUCTION.—Nothing in
 10 this section shall be construed to restrict the author-
 11 ity of the Federal Government, or of a State, to es-
 12 tablish, implement, and enforce requirements and re-
 13 strictions with respect to abortion drugs under provi-
 14 sions of law other than this section that are in addi-
 15 tion to the requirements and restrictions under this
 16 section.

17 “(5) DEFINITIONS.—In this section:

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

1 known to be pregnant, with an intention other
 2 than—

3 “(i) to produce a live birth;

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

5 or

6 “(iii) to treat an ectopic pregnancy.

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

9 “(i) A fatality.

10 “(ii) An ectopic pregnancy.

11 “(iii) A hospitalization.

12 “(iv) A blood loss requiring a trans-
 13 fusion.

14 “(v) An infection, including endo-
 15 metritis, pelvic inflammatory disease, and
 16 pelvic infections with sepsis.

17 “(vi) A severe infection.

18 “(C) The term ‘gestation’ means the pe-
 19 riod of days of pregnancy beginning on the first
 20 day of the last menstrual period.

21 “(D) The term ‘health care practitioner’
 22 means any individual who is licensed, reg-
 23 istered, or otherwise permitted, by the United
 24 States or the jurisdiction in which the indi-

1 vidual practices, to prescribe drugs subject to
2 section 503(b)(1).

3 “(E) The term ‘unborn child’ means an in-
4 dividual organism of the species homo sapiens,
5 beginning at fertilization, until the point of
6 being born alive as defined in section 8(b) of
7 title 1, United States Code.”.

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

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