

117TH CONGRESS  
2D SESSION

# S. 4638

To allow women greater access to safe and effective oral contraceptive drugs  
intended for routine use.

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## IN THE SENATE OF THE UNITED STATES

JULY 27, 2022

Ms. ERNST (for herself and Mr. GRASSLEY) introduced the following bill;  
which was read twice and referred to the Committee on Health, Edu-  
cation, Labor, and Pensions

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## A BILL

To allow women greater access to safe and effective oral  
contraceptive drugs intended for routine use.

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 “Allowing Greater Ac-  
5 cess to Safe and Effective Contraception Act”.

6 **SEC. 2. SUPPLEMENTAL APPLICATIONS FOR OVER-THE-**  
7 **COUNTER CONTRACEPTIVE DRUGS.**

8 (a) PRIORITY REVIEW OF APPLICATION.—The Sec-  
9 retary of Health and Human Services (referred to in this  
10 section as the “Secretary”) shall give priority review to

1 any supplemental application submitted under section  
2 505(b) of the Federal Food, Drug, and Cosmetic Act (21  
3 U.S.C. 355(b)) if—

4 (1) the supplemental application is with respect  
5 to an oral contraceptive drug intended for routine  
6 use;

7 (2) the supplemental application is not with re-  
8 spect to any emergency contraceptive drug;

9 (3) the supplemental application is not with re-  
10 spect to any drug that is also approved for induced  
11 abortion; and

12 (4) if the supplemental application is approved,  
13 with respect to individuals aged 18 and older, such  
14 drug would not be subject to section 503(b)(1) of  
15 the Federal Food, Drug, and Cosmetic Act (21  
16 U.S.C. 353(b)(1)).

17 (b) FEE WAIVER.—The Secretary shall waive the fee  
18 under section 736(a)(1) of the Federal Food, Drug, and  
19 Cosmetic Act (21 U.S.C. 379h(a)(1)) with respect to a  
20 supplemental application that receives priority review  
21 under subsection (a).

22 (c) OVER-THE-COUNTER AVAILABILITY.—Notwith-  
23 standing any other provision of law, with respect to indi-  
24 viduals under age 18, a contraceptive drug that is eligible  
25 for priority review under subsection (a) shall be subject

1 to section 503(b)(1) of the Federal Food, Drug, and Cos-  
2 metic Act (21 U.S.C. 353(b)(1)), including after approval  
3 of the supplemental application as described in subsection  
4 (a)(3).

5 (d) APPLICABILITY.—This section applies with re-  
6 spect to a supplemental application described in subsection  
7 (a) that—

8 (1) is submitted before the date of enactment of  
9 this Act and remains pending as of such date of en-  
10 actment; or

11 (2) is submitted after such date of enactment.

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