

117TH CONGRESS
2D SESSION

H. R. 8428

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

IN THE HOUSE OF REPRESENTATIVES

JULY 19, 2022

Mrs. HINSON (for herself, Mrs. MILLER-MEEKS, Ms. MACE, Mrs. RODGERS of Washington, and Mr. SMITH of Missouri) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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”.

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

3 (a) **PRIORITY REVIEW OF APPLICATION.**—The Sec-
4 retary of Health and Human Services (referred to in this
5 section as the “Secretary”) shall give priority review to
6 any supplemental application submitted under section
7 505(b) of the Federal Food, Drug, and Cosmetic Act (21
8 U.S.C. 355(b)) if—

9 (1) the supplemental application is with respect
10 to an oral contraceptive drug intended for routine
11 use;

12 (2) the supplemental application is not with re-
13 spect to any emergency contraceptive drug; and

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

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

24 (c) **OVER-THE-COUNTER AVAILABILITY.**—Notwith-
25 standing any other provision of law, with respect to indi-
26 viduals under age 18, a contraceptive drug that is eligible

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

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

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

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

13 **SEC. 3. EMPOWERING WOMEN TO MAKE THEIR OWN**
14 **HEALTH DECISIONS.**

15 (a) **REPEAL OF LIMITATIONS ON CONTRIBUTIONS TO**
16 **FLEXIBLE SPENDING ACCOUNTS.**—Section 125 of the In-
17 ternal Revenue Code of 1986 is amended by striking sub-
18 section (i).

19 (b) **WAIVER OF STOCKPILING RULES.**—The Sec-
20 retary of the Treasury (or the Secretary’s delegate) shall
21 issue regulations or other guidance, or revise regulations
22 and other guidance as necessary, to provide that for pur-
23 poses of health savings accounts under section 223 of the
24 Internal Revenue Code of 1986, Archer MSAs under sec-
25 tion 220 of such Code, and health flexible spending ar-

1 rangements and health reimbursement arrangements for
2 purposes of sections 106 and 125 of such Code, rules pro-
3 hibiting the purchase of multiples of any item or limiting
4 the number of an item which can be purchased shall not
5 apply to purchases of oral contraceptive drugs described
6 in section 2(a)(1).

7 (c) EFFECTIVE DATE.—The amendment made by
8 subsection (a) shall apply to taxable years beginning after
9 December 31, 2021.

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