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118TH CONGRESS
1ST SESSION

H. R. 1512

To allow women greater access to a wider range of self-administered contraceptives approved under the Federal Food, Drug, and Cosmetic Act.

IN THE HOUSE OF REPRESENTATIVES

MARCH 9, 2023

Ms. MACE introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To allow women greater access to a wider range of self-administered contraceptives approved under the Federal Food, Drug, and Cosmetic Act.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Greater Access to Contraceptive Options Act''.

SEC. 2. APPLICATIONS FOR NON-PRESCRIPTION CONTRACEPTIVE METHODS.

(a) PRIORITY REVIEW OF APPLICATION.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall give priority review to

any supplemental application submitted under section 505(b), 510(k), or 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b), 360, 360e) for a self-administered contraceptive method to be marketed without being subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)) or treated as a prescription device.

(b) FEE WAIVER.—The Secretary shall waive the fee under section 736(a)(1) or 738(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(a)(1); 379j(a)(2)) (as applicable) with respect to a supplemental application that receives priority review under subsection (a).

(c) APPLICABILITY.—This section applies with respect to a supplemental application described in subsection (a) that—

(1) is submitted before the date of enactment of this Act and remains pending as of such date of enactment; or

(2) is submitted after such date of enactment.

(d) SELF-ADMINISTERED CONTRACEPTIVE METHOD DEFINED.—In this Act, the term ''self-administered contraceptive method'' means a drug or device (as those terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)) or combination product ap-

proved for use under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.) as a method of contraception that is administered without the intervention of a health care professional, including the birth control pill, patch, vaginal ring, or injection, such as depot medroxyprogesterone acetate.

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