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118TH CONGRESS
1ST SESSION

H. R. 4626

To encourage sponsors of oral contraceptive drugs to submit applications for the approval of such drugs as over-the-counter, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 13, 2023

Mrs. MILLER-MEEKS (for herself, Mrs. KIGGANS of Virginia, Ms. GREENE of Georgia, Mrs. BICE, Ms. SALAZAR, Mrs. CHAVEZ-DEREMER, Ms. MALLIOTAKIS, Mrs. KIM of California, Mrs. HARSHBARGER, and Ms. MACE) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To encourage sponsors of oral contraceptive drugs to submit applications for the approval of such drugs as over-the-counter, and for other purposes.

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 ''Orally Taken Contraception Act of 2023'' or the ''OTC Act of 2023''.

SEC. 2. FDA GUIDANCE ON CHANGING MARKETING STATUS OF CONTRACEPTIVE DRUGS TO OVER-THE-COUNTER.

(a) IN GENERAL.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services acting through the Commissioner of Food and Drugs, for purposes of encouraging sponsors of oral contraceptive drugs to submit applications for the approval of oral contraceptive drugs 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)), shall issue guidance that—

(1) provides a detailed description of the review process for the—

(A) approval of drugs under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355);

(B) marketing authorization of over-the-counter drugs under section 505G of such Act (21 U.S.C. 355h); and

(C) licensure of biological products under section 351 of the Public Health Service Act (42 U.S.C. 262);

(2) provides for background information on oral contraceptive drugs, including—

(A) the history of approval, marketing authorization, or licensure of oral contraceptive drugs under the provisions of law specified in paragraph (1);

(B) the standards used to grant such approval, marketing authorization, or licensure; and

(3) specifies the benefit-risk considerations that the Secretary uses to determine whether to approve, authorize for marketing, or license oral contraceptive drugs; and

(4) details the Secretary's efforts to facilitate the development of oral contraceptive drugs 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)).

(b) LABELING COMPREHENSION STUDY.—

(1) IN GENERAL.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall complete a study on consumer comprehension of the labeling of oral contraceptive drugs.

(2) ISSUES TO BE STUDIED.—The study required by paragraph (1) shall address how the labeling of oral contraceptive drugs could be improved to

increase consumer comprehension of the information conveyed in such labeling, including the proper use of such drugs and for whom such drugs are indicated.

(3) COMPLETION; PUBLICATION.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall—

(A) not later than 1 year after the date of the enactment of this Act, complete the study required by paragraph (1); and

(B) publish the results of such study in conjunction with the issuance of the guidance required by subsection (a).

(c) ORAL CONTRACEPTIVE DRUG DEFINED.—In this section, the term ''oral contraceptive drug'' means a drug (as defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)) that—

(1) is used to prevent fertilization;

(2) is administered orally;

(3) is solely intended for routine use and not as an emergency contraceptive;

(4) does not include any drug, substance, or combination of drugs or substances used after fertilization; and

(5) does not include any drug or other method used to terminate a pregnancy.

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