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114TH CONGRESS
1ST SESSION

H. R. 3163

To ensure timely access to affordable birth control for women.

IN THE HOUSE OF REPRESENTATIVES

JULY 22, 2015

Ms. DUCKWORTH (for herself, Mr. CROWLEY, Mr. MURPHY of Florida, Mr. RANGEL, Mr. GRIJALVA, Ms. NORTON, Mr. PAYNE, Ms. CLARK of Massachusetts, Mr. BERA, Mr. TED LIEU of California, Mr. MCDERMOTT, Mr. POCAN, Mr. BLUMENAUER, Ms. BONAMICI, Mrs. WATSON COLEMAN, Mr. RYAN of Ohio, Mr. NADLER, Ms. DEGETTE, Ms. FRANKEL of Florida, Ms. CASTOR of Florida, Ms. DELBENE, Mr. DEUTCH, Ms. SLAUGHTER, Mr. LEWIS, Mrs. BEATTY, Mr. BEYER, Ms. WASSERMAN SCHULTZ, Mr. DAVID SCOTT of Georgia, Miss RICE of New York, Mr. ELLISON, Ms. JACKSON LEE, Ms. SPEIER, Mr. GRAYSON, Mrs. DAVIS of California, Mr. CUMMINGS, Mrs. CAPPS, Ms. KUSTER, Ms. CLARKE of New York, Ms. SCHAKOWSKY, Ms. DELAURO, Mr. WELCH, Ms. HAHN, Ms. WILSON of Florida, Mr. ENGEL, Mr. HONDA, Mr. COHEN, Ms. EDWARDS, Mr. MOULTON, Ms. PINGREE, Ms. TITUS, Mr. PETERS, Mr. HASTINGS, Mr. VAN HOLLEN, Mr. CAPUANO, Mr. BRENDAN F. BOYLE of Pennsylvania, Mr. CONYERS, Mr. SEAN PATRICK MALONEY of New York, Mr. DESAULNIER, Mr. CÁRDENAS, Mr. TONKO, Ms. MOORE, Mrs. LAWRENCE, Mr. DEFAZIO, Ms. BROWNLEY of California, Mr. QUIGLEY, Ms. MCCOLLUM, Mrs. BUSTOS, Ms. LEE, Mr. LARSEN of Washington, Ms. MICHELLE LUJAN GRISHAM of New Mexico, Mr. BRADY of Pennsylvania, Mr. DANNY K. DAVIS of Illinois, Mr. JOHNSON of Georgia, Ms. JUDY CHU of California, Mr. O'ROURKE, Mr. LOEBSACK, and Ms. ROYBAL-ALLARD) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To ensure timely access to affordable birth control for women.

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 ''Affordability Is Access Act''.

SEC. 2. PURPOSE.

The purpose of this Act is to ensure timely access to affordable birth control by requiring coverage without cost-sharing for oral birth control for routine, daily use that is approved by, or otherwise legally marketed under regulation by, the Food and Drug Administration for use by women without a prescription.

SEC. 3. FINDINGS.

Congress makes the following findings:

(1) Access to the full range of health benefits and preventive services, including access to birth control, as guaranteed under Federal law, provides all people of the United States with the opportunity to lead healthier and more productive lives.

(2) Birth control is a critical health care benefit and service for women. Almost all women use birth control at some point in their lifetimes. The Centers for Disease Control and Prevention declared it one of the Ten Great Public Health Achievements of the 20th Century.

(3) Birth control prevents and reduces unintended pregnancies and provides many health and socioeconomic benefits for women. Women with access to birth control are more likely to have higher educational and career achievement, and to earn higher wages.

(4) Affordability and timely access have long been barriers for women being able to use birth control. Many women struggle to obtain the birth control they need because of cost or other access barriers, which has contributed to the high unintended pregnancy rate in the United States. A national survey found that 1 in 3 women have struggled to afford birth control at some point in their lives, and as a result, have used birth control inconsistently. The rate is even higher for young women who are most likely to experience an unintended pregnancy.

(5) Three separate studies have found that lack of health coverage is significantly associated with reduced use of prescription contraceptive methods, including birth control.

(6) The Patient Protection and Affordable Care Act (Public Law 111–148) sought to remove barriers to care and improve access by requiring all new health plans to cover recommended preventive serv-

ices without cost-sharing, which include women's preventive services, including all contraceptive methods, including birth control and sterilization for women approved by the Food and Drug Administration and related education and counseling.

(7) The Patient Protection and Affordable Care Act women's preventive services benefit has significantly improved women's access to birth control, including oral birth control for routine, daily use. The Department of Health and Human Services has reported that, as of 2014, more than 55,000,000 women are benefitting from coverage without cost-sharing for women's preventive services, including birth control, under the Patient Protection and Affordable Care Act. Women have saved more than $483,000,000 in out-of-pocket costs for birth control with no copayments in 2012 compared to 2013, an average savings of $269 per woman.

(8) The most appropriate method of birth control varies according to each individual woman's needs, medical history, and stage of life. For instance, women may have medical contraindications that limit their ability to use certain birth control methods. It is critical that the full range of birth control methods approved by the Food and Drug

Administration are available and covered without cost-sharing in order to ensure that each woman has access to the birth control method that best meets her needs.

(9) The determination as to whether a drug should be available for use without a prescription is appropriately and solely made by the Food and Drug Administration. To ensure the safety and efficacy of a drug, including a drug available for over-the-counter use, the appropriate scientific and medical personnel at the Food and Drug Administration, often with input from independent advisory panels of experts, review clinical and other data relating to the safety and efficacy of the drug. This scientific and medical review can occur as part of the Food and Drug Administration's over-the-counter drug review for potential inclusion in a monograph as generally recognized as safe and effective, or as part of the review of a new drug application (or an abbreviated new drug application). As part of these regulatory processes, the appropriate scientific and medical personnel review clinical and other data, including data generated in controlled clinical trials. The Food and Drug Administration also reviews consumer studies and monitors post-marketing safety data. All of

these processes ensure that the appropriate scientific and medical personnel make the determination of safety, quality, and efficacy of drugs marketed to the people of the United States.

(10) Leading women's health experts, providers, and medical associations, including the American College of Obstetricians and Gynecologists and the American Academy of Family Physicians, support full insurance coverage and increased access to oral birth control over-the-counter. In 2012, the American College of Obstetricians and Gynecologists issued a Committee Opinion recommending approval by the Food and Drug Administration of certain forms of birth control for over-the-counter use to increase timely access to birth control. Furthermore, data demonstrates that birth control that is available over-the-counter has public support and would increase birth control usage and continuation. The Committee Opinion followed similar recommendations made by leading reproductive health experts and published in the American Journal of Public Health.

(11) Research shows that birth control available over-the-counter, as an addition to, not a substitute for, the women's preventive health benefit under the

Patient Protection and Affordable Care Act, would increase accessibility for oral birth control for routine, daily use.

SEC. 4. SENSE OF THE HOUSE OF REPRESENTATIVES.

It is the sense of the House of Representatives that—

(1) in order to increase women's access to oral birth control, it must be both easier to obtain and affordable and, to make it either easier to obtain or more affordable, but not both, is to leave unacceptable barriers in place for women;

(2) it is imperative that the entities that research and develop oral birth control and whose medical and scientific experts have developed clinical and other evidence that oral birth control for routine, daily use is safe and effective for women when sold without a prescription, apply to the Food and Drug Administration for review and approval for sale of such birth control without a prescription;

(3) upon the receipt of such an application, the Food and Drug Administration should determine whether the oral birth control meets the rigorous safety, efficacy, and quality standards for over-the-counter use under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), and if the product meets those standards, the Food and Drug Ad-

ministration should approve the application without delay; and

(4) if and when the Food and Drug Administration approves an oral birth control that is available over-the-counter, such birth control should be covered by health insurance, without a prescription and without cost-sharing.

SEC. 5. ENSURING COVERAGE OF ORAL BIRTH CONTROL FOR USE WITHOUT A PRESCRIPTION.

Section 2713(a)(4) of the Public Health Service Act (42 U.S.C. 300gg–13(a)(4)) is amended by inserting ''(including oral contraceptives for routine, daily use approved by the Food and Drug Administration for use without a prescription, even if the individual does not have a prescription for such contraceptive)'' after ''additional preventive care''.

SEC. 6. RULES OF CONSTRUCTION.

(a) NON-INTERFERENCE WITH FDA REGULATION.—Nothing in this Act (or the amendment made by this Act) shall be construed to modify or interfere with Food and Drug Administration processes to review or approve, or otherwise determine the safety and efficacy of, and make available, non-prescription drugs or devices, modify or interfere with the scientific and medical consid-

erations of the Food and Drug Administration, or alter any other authority of the Food and Drug Administration.

(b) NON-PREEMPTION.—Nothing in this Act (or the amendment made by this Act) preempts any provision of Federal or State law to the extent that such Federal or State law provides protections for consumers that are greater than the protections provided for in this Act.

SEC. 7. DUTIES OF RETAILERS TO ENSURE ACCESS TO ORAL BIRTH CONTROL FOR USE WITHOUT A PRESCRIPTION.

(a) IN GENERAL.—Any retailer that stocks oral birth control for routine, daily use that is approved by, or otherwise legally marketed under regulation by, the Food and Drug Administration for use without a prescription may not interfere with an individual's access to or purchase of such birth control or access to medically accurate, comprehensive information about such birth control.

(b) LIMITATION.—Nothing in this section shall prohibit a retailer that stocks oral birth control for routine, daily use from refusing to provide an individual with such oral birth control that is approved by, or otherwise legally marketed under regulation by, the Food and Drug Administration if the individual is unable to pay for the birth control, directly or through insurance coverage.

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