

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

A BILL

To ensure timely access to affordable birth control for women.

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 “Affordability Is Access
5 Act”.

6 **SEC. 2. PURPOSE.**

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

13 **SEC. 3. FINDINGS.**

14 Congress makes the following findings:

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

20 (2) Birth control is a critical health care benefit
21 and service for women. Almost all women use birth
22 control at some point in their lifetimes. The Centers
23 for Disease Control and Prevention declared it one
24 of the Ten Great Public Health Achievements of the
25 20th Century.

1 (3) Birth control prevents and reduces unin-
2 tended pregnancies and provides many health and
3 socioeconomic benefits for women. Women with ac-
4 cess to birth control are more likely to have higher
5 educational and career achievement, and to earn
6 higher wages.

7 (4) Affordability and timely access have long
8 been barriers for women being able to use birth con-
9 trol. Many women struggle to obtain the birth con-
10 trol they need because of cost or other access bar-
11 riers, which has contributed to the high unintended
12 pregnancy rate in the United States. A national sur-
13 vey found that 1 in 3 women have struggled to af-
14 ford birth control at some point in their lives, and
15 as a result, have used birth control inconsistently.
16 The rate is even higher for young women who are
17 most likely to experience an unintended pregnancy.

18 (5) Three separate studies have found that lack
19 of health coverage is significantly associated with re-
20 duced use of prescription contraceptive methods, in-
21 cluding birth control.

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

1 ices without cost-sharing, which include women's
2 preventive services, including all contraceptive meth-
3 ods, including birth control and sterilization for
4 women approved by the Food and Drug Administra-
5 tion and related education and counseling.

6 (7) The Patient Protection and Affordable Care
7 Act women's preventive services benefit has signifi-
8 cantly improved women's access to birth control, in-
9 cluding oral birth control for routine, daily use. The
10 Department of Health and Human Services has re-
11 ported that, as of 2014, more than 55,000,000
12 women are benefitting from coverage without cost-
13 sharing for women's preventive services, including
14 birth control, under the Patient Protection and Af-
15 fordable Care Act. Women have saved more than
16 \$483,000,000 in out-of-pocket costs for birth control
17 with no copayments in 2012 compared to 2013, an
18 average savings of \$269 per woman.

19 (8) The most appropriate method of birth con-
20 trol varies according to each individual woman's
21 needs, medical history, and stage of life. For in-
22 stance, women may have medical contraindications
23 that limit their ability to use certain birth control
24 methods. It is critical that the full range of birth
25 control methods approved by the Food and Drug

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

5 (9) The determination as to whether a drug
6 should be available for use without a prescription is
7 appropriately and solely made by the Food and Drug
8 Administration. To ensure the safety and efficacy of
9 a drug, including a drug available for over-the-
10 counter use, the appropriate scientific and medical
11 personnel at the Food and Drug Administration,
12 often with input from independent advisory panels of
13 experts, review clinical and other data relating to the
14 safety and efficacy of the drug. This scientific and
15 medical review can occur as part of the Food and
16 Drug Administration's over-the-counter drug review
17 for potential inclusion in a monograph as generally
18 recognized as safe and effective, or as part of the re-
19 view of a new drug application (or an abbreviated
20 new drug application). As part of these regulatory
21 processes, the appropriate scientific and medical per-
22 sonnel review clinical and other data, including data
23 generated in controlled clinical trials. The Food and
24 Drug Administration also reviews consumer studies
25 and monitors post-marketing safety data. All of

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

5 (10) Leading women’s health experts, providers,
6 and medical associations, including the American
7 College of Obstetricians and Gynecologists and the
8 American Academy of Family Physicians, support
9 full insurance coverage and increased access to oral
10 birth control over-the-counter. In 2012, the Amer-
11 ican College of Obstetricians and Gynecologists
12 issued a Committee Opinion recommending approval
13 by the Food and Drug Administration of certain
14 forms of birth control for over-the-counter use to in-
15 crease timely access to birth control. Furthermore,
16 data demonstrates that birth control that is available
17 over-the-counter has public support and would in-
18 crease birth control usage and continuation. The
19 Committee Opinion followed similar recommenda-
20 tions made by leading reproductive health experts
21 and published in the American Journal of Public
22 Health.

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

1 Patient Protection and Affordable Care Act, would
2 increase accessibility for oral birth control for rou-
3 tine, daily use.

4 **SEC. 4. SENSE OF THE HOUSE OF REPRESENTATIVES.**

5 It is the sense of the House of Representatives that—

6 (1) in order to increase women’s access to oral
7 birth control, it must be both easier to obtain and
8 affordable and, to make it either easier to obtain or
9 more affordable, but not both, is to leave unaccept-
10 able barriers in place for women;

11 (2) it is imperative that the entities that re-
12 search and develop oral birth control and whose
13 medical and scientific experts have developed clinical
14 and other evidence that oral birth control for rou-
15 tine, daily use is safe and effective for women when
16 sold without a prescription, apply to the Food and
17 Drug Administration for review and approval for
18 sale of such birth control without a prescription;

19 (3) upon the receipt of such an application, the
20 Food and Drug Administration should determine
21 whether the oral birth control meets the rigorous
22 safety, efficacy, and quality standards for over-the-
23 counter use under the Federal Food, Drug, and Cos-
24 metic Act (21 U.S.C. 301 et seq.), and if the prod-
25 uct meets those standards, the Food and Drug Ad-

1 ministration should approve the application without
2 delay; and

3 (4) if and when the Food and Drug Adminis-
4 tration approves an oral birth control that is avail-
5 able over-the-counter, such birth control should be
6 covered by health insurance, without a prescription
7 and without cost-sharing.

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

10 Section 2713(a)(4) of the Public Health Service Act
11 (42 U.S.C. 300gg–13(a)(4)) is amended by inserting “(in-
12 cluding oral contraceptives for routine, daily use approved
13 by the Food and Drug Administration for use without a
14 prescription, even if the individual does not have a pre-
15 scription for such contraceptive)” after “additional pre-
16 ventive care”.

17 **SEC. 6. RULES OF CONSTRUCTION.**

18 (a) NON-INTERFERENCE WITH FDA REGULA-
19 TION.—Nothing in this Act (or the amendment made by
20 this Act) shall be construed to modify or interfere with
21 Food and Drug Administration processes to review or ap-
22 prove, or otherwise determine the safety and efficacy of,
23 and make available, non-prescription drugs or devices,
24 modify or interfere with the scientific and medical consid-

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

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

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

11 (a) IN GENERAL.—Any retailer that stocks oral birth
12 control for routine, daily use that is approved by, or other-
13 wise legally marketed under regulation by, the Food and
14 Drug Administration for use without a prescription may
15 not interfere with an individual’s access to or purchase
16 of such birth control or access to medically accurate, com-
17 prehensive information about such birth control.

18 (b) LIMITATION.—Nothing in this section shall pro-
19 hibit a retailer that stocks oral birth control for routine,
20 daily use from refusing to provide an individual with such
21 oral birth control that is approved by, or otherwise legally
22 marketed under regulation by, the Food and Drug Admin-
23 istration if the individual is unable to pay for the birth
24 control, directly or through insurance coverage.

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