

The Devil Is in the Details: Reviewing OTC Birth Control Efforts in Congress and Their Potential Impacts

By Courtney Joslin and Sophia Heimowitz



Expanding the OTC contraceptive market can broaden access, improve consumer choice, drive down costs and allow women to make the contraceptive decisions that work best for them.

Introduction

With the reproductive health landscape taking center stage in the political arena once again, many are looking for ways to improve access to contraception. Concerns over access for the millions of women who rely on birth control are bipartisan; in recent years, both Republicans and Democrats in Congress have introduced their own legislation that aims to improve access to hormonal birth control through over-the-counter (OTC) availability.¹

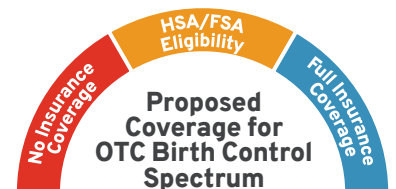
Although policymakers from both parties believe that hormonal birth control, such as the pill, should be available OTC, they disagree on insurance coverage.² A recent proposal from Democrats in Congress would mandate that, if a birth control pill were to become available OTC, it must be fully covered by insurance.³ Their Republican counterparts opposed this and have offered their own solutions that stop short of full insurance coverage.⁴ Putting the full-or-no insurance coverage debate aside, proposals in Congress that aim to fast track an OTC birth control pill are worth examining for their potential impact.

This paper explores proposals in Congress's recent past from Republican members that urge the U.S. Food and Drug Administration (FDA) to fast track an OTC pill option, as well as the potential cost implications of those proposals to consumers. With this information, policymakers will be able to work toward bipartisan solutions.

A Timeline of Recent Efforts in Congress on OTC Birth Control

The "Allowing Greater Access to Safe and Effective Contraception Act" was first introduced in 2015 by Sen. Kelly Ayotte (R-N.H.) and directed the FDA to prioritize and waive fees for OTC contraceptive drug applications.⁵ It also would have repealed provisions of the Patient Protection and Affordable Care Act (ACA) and the Health Care and Education Reconciliation Act of 2010 to allow funds from health savings accounts (HSAs) and flexible spending accounts (FSAs) to be used to pay for nonprescription medication. Of note, any contraceptive drugs approved for OTC use would still require a prescription for users under age 18. The bill was referred to the finance committee and stalled.⁶

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In 2017, Sen. Joni Ernst (R-Iowa) and Rep. Mia Love (R-Utah) introduced identical bills to the 2015 Senate version in their respective chambers.⁷ Both bills stalled in committee.

In 2019, Sen. Ernst again introduced a Senate version of the bill.⁸ This version expanded the use of HSAs, medical savings accounts (MSAs) and employer reimbursements for OTC medications. Similar to prior versions of the bill, this bill required the FDA to give no-cost priority review to OTC applications for already-approved contraceptive drugs, although these drugs would still require a prescription for individuals under the age of 18.⁹

Most recently, in 2022, identically titled bills were introduced in the Senate by Sen. Ernst and the House by Rep. Ashley Hinson (R-Iowa).¹⁰ Sen. Ernst’s bill removed the HSA/extended payment component of previous bills and specified that the only drugs eligible for priority review would be oral contraceptives and emergency contraceptives. Rep. Hinson’s bill also specified oral contraceptives as the only drugs eligible for priority review, excluded emergency contraception, and allowed the use of HSAs and similar FSAs to cover them. The fee waiver and 18-year-old age minimum for OTC access stayed in both versions.¹¹

Although none of these bills made it out of committee, the primary components of these efforts were to urge the FDA to fast track manufacturer applications for OTC birth control pills, waive the associated fees to impose less of a financial burden to applicants and allow for various health care-related savings accounts to cover OTC birth control.

Improving Access and Reducing Costs

To examine the ways in which access and cost would be affected by OTC birth control pills, it is important to consider the primary groups of individuals this change would affect. First, this shift in access would benefit uninsured individuals who are less likely to be under the care of a health care provider than the insured.¹² Second, HSA and FSA holders would see cost savings.

Better Access and Improved Affordability for Those Without Insurance Coverage

If a pill were to become available OTC, it would likely provide a more accessible hormonal contraceptive option for the uninsured population. The Assistant Secretary of Planning and Evaluation (ASPE) estimated that nearly 7.9 million women of reproductive age in the United States do not currently have insurance.¹³ Although the ACA did increase the number of insured individuals, it did not fully eliminate the uninsured issue. For those currently uninsured, recent survey data found that the primary reason was cost.¹⁴

If cost is a barrier to insurance, then it is also certainly a barrier to obtaining birth control. For an uninsured woman in the United States, the mean cost of a primary care visit is \$186.¹⁵ If prescribed, birth control pills would also be a monthly out-of-pocket cost. Since it is likely that the first OTC birth control pill would be a progestin-only version, the cash prices for 30-day supplies of progestin-only pills on the market are below.

Table 1: Average Cost of a 30-Day Supply of Progestin-Only Pills Without Insurance

Drug Name	Monthly Cost
Norethindrone	\$35
Errin®	\$37
Heather®	\$36
Norlyda®	\$31

Source: Sasha Guttentag, “The Annual Cost of Birth Control,” GoodRX Health, April 6, 2021. <https://www.goodrx.com/conditions/birth-control/annual-cost-of-birth-control>.

It is estimated that nearly **7.9 million** United States women of reproductive age do not currently have insurance.

Assuming an individual would require an annual doctor’s visit to maintain a valid prescription and would adhere to the continued use of a progestin-only pill over 12 months, the estimated annual average cost for a birth control pill regimen to an uninsured patient would be \$603. With the prescription requirement removed, the estimated annual cost of an OTC pill to an uninsured patient would be reduced to \$417.

Improved Affordability with FSA/HSA Coverage

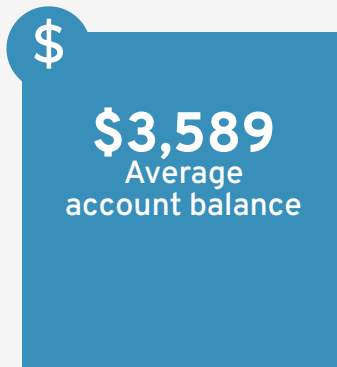
As noted previously, iterations of the Congressional efforts have included provisions allowing funds from certain health care-related savings accounts to cover the cost of OTC birth control. Under these proposals, FSAs, HSAs, MSAs and health reimbursement arrangements (HRAs) are all valid options for covering the cost of OTC birth control. These savings accounts make it easier to afford health care-related expenses not covered by insurance, and the majority enable individuals to contribute pretax dollars to spend on future health care costs.¹⁶ Thus, pretax dollars could be used to pay the estimated \$417 annual cost of OTC birth control. It is unclear, however, how many of those who have such accounts would take the OTC route if insurance covered a doctor’s visit copay and prescriptions, so further research is needed to understand the cost-savings implications of this structure.

Historically, OTC medications have not been considered qualified medical expenses for these savings accounts. However, under the Coronavirus Aid, Relief, and Economic Security (CARES) Act of 2020, OTC drugs became eligible for FSA/HSA coverage. If extended to an OTC birth control pill, this would become a payment option for millions of FSA and HSA holders.¹⁷ Funds in these accounts can also be used for people other than the account holder, making them somewhat more flexible for covering the cost of birth control in a household.

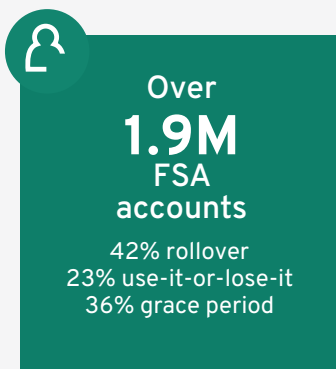
Uninsured 12-Month Cost Benefits for OTC Birth Control Pills

\$603* Doc visit required	\$417* OTC access
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*Estimated Annual Average Cost



Source: “2022 Midyear HSA Market Statistics and Trends Executive Summary,” Devenir Research, Sept. 9, 2022. <https://www.devenir.com/wp-content/uploads/2022-Midyear-Devenir-HSA-Research-Report-Executive-Summary.pdf>.



As of Dec. 31, 2020

Source: “FSA Database,” Employee Benefit Research Institute, last accessed Jan. 28, 2023. <https://www.ebri.org/health/fsa-database>.

Enhanced Competition, Lower Costs: Lessons from Emergency Contraception

Although the average annual out-of-pocket cost of an OTC progestin-only birth control pill for an uninsured individual is estimated to be \$417, this cost assumes current options and pricing and does not account for the potential expansion of options due to competition. However, experience with emergency contraception has shown that when competition is introduced in an OTC market, prices fall.

Plan B was initially a two-pill emergency contraceptive designed to be used within 72 hours after contraceptive failure, misuse or nonuse. In August 2006, the FDA announced that the emergency contraceptive pills had been approved for OTC sales to individuals 18 and older.¹⁸ Then, in 2013, the FDA approved the one-pill version (Plan B One-Step) for OTC status without an age restriction and with exclusive marketing rights for three years.¹⁹ At the time, Plan B One-Step was the only emergency contraceptive available OTC, and it cost around \$50.²⁰ However, once the three-year exclusivity expired, generic versions entered the OTC market, and this emergency contraception is now available in a variety of generic versions for as low as \$7.50 (Table 2).

Table 2: Emergency Contraception Prices

Brand	Current Low Price (Pharmacy)	Active Ingredient
Plan B One-Step	\$49 (Walgreens & CVS)	Levonorgestrel 1.5 mg
Take Action	\$39 (Walgreens)	Levonorgestrel 1.5 mg
Aftera	\$29 (CVS)	Levonorgestrel 1.5 mg
MY Way	\$33 (Amazon)	Levonorgestrel 1.5 mg
Option 2	\$17 (Amazon)	Levonorgestrel 1.5 mg
Aurohealth E-Con Morning After	\$8.87 (Amazon)	Levonorgestrel 1.5 mg
My Choice	\$8.75 (Amazon)	Levonorgestrel 1.5 mg
FemChoice	\$9.99 (Amazon)	Levonorgestrel 1.5 mg
Rugby	\$7.50 (Amazon)	Levonorgestrel 1.5 mg

Source: Compiled prices from Walgreens, CVS and Amazon, last accessed Jan. 20, 2022.

Thus, if a progestin-only birth control pill were to become available on the OTC market, its initial average price of \$34.75 may not budge. But if generic versions were allowed to enter the market as well, the price will likely fall as it did with emergency contraception, making it even more affordable.

Potential Uptake of OTC Birth Control

While it is not clear how many uninsured individuals or HSA/FSA account holders would take advantage of OTC birth control if it were to become available, recent survey data provides insight on the primary reasons consumers want the option. Perhaps not surprisingly, the primary reason uninsured survey respondents reported they would switch to OTC birth control is convenience (51 percent), followed by potential cost savings (16 percent).²¹ However, when given price parameters to consider, the majority of uninsured female survey respondents (79 percent) said they were only willing and able

KEY TAKEAWAY

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to pay less than \$20 for monthly birth control.²² Given that the current price average of progestin-only birth control is \$34.75, generics would likely need to enter the OTC market to meet the needs of most uninsured women looking for an affordable birth control option.

Key Recommendations

Drawing from the issues discussed herein, we offer three key considerations for Congress to successfully implement OTC birth control moving forward.

First, members of Congress can continue to push for the fast tracking of OTC birth control applications. The FDA process for getting a drug on the OTC market can be costly and time consuming.²³ As a result, drug manufacturers may be hesitant to initiate the process. Congress can help reduce that barrier by fast tracking OTC contraception applications and waiving the associated fees. While this is far from the only necessary step in creating an OTC birth control market, creating these incentives may facilitate the OTC market down the road.

Second, to best support uptake for price-sensitive consumers, Congress can consider strategies that ensure generic competition is allowed to enter the market. As OTC emergency contraception has shown, allowing only one brand of drug to enter the OTC market does little to nothing to decrease costs to consumers. This is particularly important for the uninsured, who have fewer options for low- or zero-cost birth control. To this end, Congress must be aware of any exclusive marketing rights that the FDA could grant to a manufacturer seeking OTC status for a birth control pill and understand the implications of these rights on prices.

Third, Congress can explore OTC availability for other short-acting hormonal contraceptives like the combination pill, patch, ring and injection—all of which are safe and effective enough to be considered for the OTC market—and urge the FDA to also consider OTC applications for these methods.

Conclusion

As members of Congress seek to secure or improve access to contraception, making birth control available OTC is a necessity. However, the devil is in the details. Cost, insurance status and competition will all intersect to affect uptake. To get the details right and achieve these goals, we encourage policymakers to continue to support fast-tracked, fee-waived applications for OTC birth control; generic competition in the OTC birth control market; and other hormonal contraception OTC options beyond the single-agent pill.²⁴ Expanding the OTC contraceptive market in this way and in line with medical recommendations can broaden access, improve consumer choice, drive down costs and allow women to make the contraceptive decisions that work best for them.

1 Continue to push for the fast tracking of applications for OTC birth control

2 Ensure that generic competition can enter the OTC market

3 Explore OTC options for other hormonal contraceptives like the combination pill, patch, ring and injection

Key Recommendations Source:
“Over-the-Counter Access to Hormonal Contraception,” The American College of Obstetricians and Gynecologists, October 2019. <https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2019/10/over-the-counter-access-to-hormonal-contraception>.

About the Authors

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