



OVER THE COUNTER

THE NEXT BIG STEP FOR BIRTH CONTROL

CENTER
FOR
REPRODUCTIVE
RIGHTS

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Center for Reproductive Rights

199 Water Street, 22nd Floor
New York, New York 10038 USA
Tel 917 637 3600
Fax 917 637 3666
publications@reprorights.org

ReproductiveRights.org
DrawTheLine.org

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We release this report in recognition of the incredible work done by the Oral Contraceptives Over-the-Counter (OCs OTC) Working Group (coordinated by Ibis Reproductive Health) to move this issue forward for over a decade. Much of the information cited in this report comes from the Working Group, and additional resources may be found at www.ocsotc.org. In addition, the Center would like to thank the following individuals for their invaluable feedback on a draft of this report: Daniel Grossman, MD, director of Advancing New Standards in Reproductive Health (ANSIRH) at the University of California San Francisco and senior advisor, Ibis Reproductive Health, and Britt Wahlin, vice president for development and public affairs at Ibis Reproductive Health.

II. Introduction

Women in the United States (U.S.) have gained unprecedented access to birth control as a result of the Affordable Care Act (ACA), which requires most private health insurance plans to cover certain preventive services for women¹ without cost-sharing (such as a copay or deductible). Included in this policy are all FDA-approved methods of birth control and necessary associated services, such as patient education and counseling. With approximately 30 million women newly eligible for private insurance that must include these benefits,² there are now over 48 million women in the U.S. eligible to receive birth control coverage without any out-of-pocket costs.³ This aspect of the law is very popular, with nearly 70% of Americans supporting the birth control policy.⁴



To the casual observer, it may seem that the story ends there. However, the truth is that the most common form of hormonal contraception—the pill—could be even more accessible if it became available over the counter (OTC) to all women. Whether someone needs birth control after office hours, over the weekend, while on vacation, or simply does not have the time or resources for a separate appointment, an OTC pill would offer accessibility and convenience for those unable or unwilling to visit a health care provider for a prescription.

Access to contraception is grounded in international human rights and is critical to an individual's ability to control his or her own life and reproduction. Moreover, making the pill more accessible is an important public health goal because more than half of all pregnancies in the United States each year are unintended.⁵

How will we achieve this next big step for birth control access in the U.S.? We know it won't be easy. The Center for Reproductive Rights fought a legal battle for over a decade to bring emergency contraception (EC) over the counter in the United States. Today, people can walk into a store, select from among several brands, and purchase EC without a prescription. Though cost barriers remain, this is a significant step forward in terms of access. But what's missing on store shelves alongside EC is an affordable daily-use birth control pill. Fortunately, researchers, health care providers, advocates and Members of Congress are all engaged in a real debate about how to make this happen.

It's time to put the pill where it belongs: on the shelf in the family planning aisle, next to condoms, spermicide, and emergency contraception. In order to reach this next frontier in birth control access, we need to be educated and united in our advocacy. This publication provides an overview of the context, legal process and critical policy considerations for making the switch from prescription to OTC status in order to move us one step closer to revolutionizing—once again—birth control choices for all women.

III. Support for an OTC Pill in the United States

Since 2004, a coalition of reproductive health, rights, and justice organizations, nonprofit research and advocacy groups, university-based researchers, and prominent clinicians has been working together as the “Oral Contraceptives Over-the-Counter (OCs OTC) Working Group” to explore the potential of OTC birth control to reduce disparities in reproductive health care and to increase women’s opportunities to access a safe, effective method of birth control.⁶ Coordinated by Ibis Reproductive Health, the coalition focuses on conducting research⁷ and public education⁸ about the risks and benefits of OTC access, building consensus on key issues, and advocating for policies in support of OTC access. Core tenets of the coalition’s agenda include a commitment to achieving OTC status free from politically motivated restrictions and to ensuring that OTC birth control is affordable to as many people as possible by advocating for public and private insurance coverage. Having witnessed the protracted and frustrating effort to bring EC over the counter, the coalition believes the optimal pathway for achieving OTC status is via a prescription-to-OTC switch application (see box below). It is therefore also focused on finding a pharmaceutical company partner to support in this endeavor.

The Process

The authority to approve medication for OTC status lies with the federal Food and Drug Administration (FDA). Pharmaceutical manufacturers or the general public can pursue OTC status for a drug through several pathways:

- *New Drug Application:* The FDA must approve a New Drug Application (NDA) for any drug introduced into the market. While it is possible for a drug to go directly over the counter, it is common for a manufacturer to first seek prescription-only status and subsequently submit additional data to apply for OTC status. In order to establish that a prescription-only drug is safe and effective for OTC use, the manufacturer must demonstrate that it is appropriate for self-administration. Specific clinical studies known as “label comprehension,” “self-selection,” and “actual use” studies are often conducted to demonstrate that consumers can read, understand, self-diagnose and self-treat according to the uses, directions, and warnings on a product’s label. This is the most likely pathway for moving a pill over the counter.
- *OTC Drug Monograph:* Certain exemptions from the OTC application process exist for drugs that are already recognized as safe and effective. The FDA compiles drug monographs that establish what kinds of ingredients may be used to treat certain diseases or conditions without a prescription. If the standards of an applicable monograph are met, a product does not need to be pre-cleared by the FDA before being sold over the counter. There is no OTC monograph available for oral contraceptives.
- *Citizen Petition:* Anyone can also petition the FDA to consider a status change for a drug. The FDA must still evaluate its safety and efficacy for OTC use; this option simply allows the public to request FDA action instead of waiting for a drug manufacturer to apply for OTC status. This option was not successful in the context of emergency contraception (see page 9).

“Weighing the risks versus the benefits based on currently available data, OCs should be available over-the-counter.”

- ACOG Committee Opinion No. 544 (2012)

An OTC birth control pill will increase contraceptive options by providing a more accessible and convenient alternative to prescription-only pills. Public opinion surveys indicate widespread support for an OTC pill, with 70% of Americans in favor of moving a pill over the counter.⁹ In a 2011 national survey, among women specifically at risk of unintended pregnancy, 62% indicated support for an OTC switch and 37% said they would be likely to use an OTC pill.¹⁰ Most women who were not interested in an OTC pill were simply

uninterested in using a birth control pill at all.¹¹

Of particular significance for the potential public health benefits of an OTC pill, the self-identified potential market includes women currently using a less effective method of birth control (such as condoms alone) or no method at all.¹² In addition, there is evidence that women continue using the pill for longer when it is available over the counter.¹³ As such, an OTC pill has the potential to reduce unintended pregnancy by increasing overall contraceptive use and improving the effectiveness of contraceptive use for some women.¹⁴

Women’s interest in an OTC pill is not surprising. Securing a prescription for contraception requires extra time and effort, including access to a health care provider, as compared to walking into a store and purchasing an OTC product. Instead of one trip during store hours to purchase birth control, a woman must schedule and travel to an appointment with her health care provider (assuming she has one) and then visit the store during pharmacy hours (which may differ from regular store hours) and wait for the pharmacist to fill the prescription. For women with day jobs, caregiving duties, or other responsibilities; those who live in rural or medically underserved areas; and those who lack transportation, these errands may be difficult at best and in some cases impossible. In a 2011 nationally representative survey, almost one-third of women at risk for unintended pregnancy reported facing obstacles accessing contraception.¹⁵ These included nonfinancial barriers that could be resolved by OTC access, such as difficulty obtaining an appointment or getting to a clinic; a clinician requiring a clinic visit, exam, or Pap smear; and not having a regular doctor or clinic.¹⁶

The Border Contraceptive Access Study¹

Researchers collected and compared data from women living in El Paso, TX, who either obtained birth control pills from a family planning clinic in El Paso or over the counter from a pharmacy across the border in Mexico. Women who accessed birth control across the border cited lower cost, skipping the doctor’s visit, and being able to send family members or friends to pick it up as the primary reasons for preferring OTC access.²

Women and the general public are not alone in calling for an OTC pill. Expert medical groups, including the American College of Obstetricians and Gynecologists (ACOG)¹⁷ and the American Academy of Family Physicians,¹⁸ support an OTC pill. The American Medical Association has recommended that the FDA encourage applications from pill manufacturers for an OTC switch,¹⁹ and the Women’s Health Practice and Research Network of the American College of Clinical Pharmacy supports OTC sales as long as a pharmacist is available for consultation and the product is covered by Medicaid.²⁰ In addition, the following health profession groups have endorsed the OCs OTC Working Group’s Statement of Purpose: American College of Nurse Midwives, Association of Reproductive Health Professionals, National Association of Nurse Practitioners in Women’s Health, and the Society of General Internal Medicine Women’s Health Task Force.²¹

Though many leading medical and public health organizations support an OTC switch, some clinicians and advocates share concerns about eliminating a health care visit prior to obtaining the pill. Their reasons range from worrying that women will disregard or ineffectively self-screen for contraindications, to viewing the skipped appointment as a lost opportunity to counsel about more effective and long-acting contraceptive methods or to provide other health interventions, such as STI screenings and pelvic exams.²² However, research suggests that women can effectively self-screen for contraindications prior to purchasing an OTC pill.²³ Moreover, to secure FDA approval, a manufacturer will have to demonstrate that its product is safe for OTC use.

If the clinical studies required by the FDA confirm that women can safely and effectively self-screen for contraindications and can use the product appropriately—as existing evidence suggests—birth control should not be held hostage to compel preventive health care visits or services that are not medically necessary for using the pill. Holistic preventive care remains an important goal, and the medical community can continue to promote preventive care visits even if birth control pills are offered over the counter. Under the ACA, most private insurers cannot charge a copay for an annual “well-woman” visit, eliminating one significant cost barrier to preventive care. Moreover, available data suggest that women will not stop seeing their health care provider simply because they access birth control without a prescription.²⁴

Making the Case: Human Rights and Global Context

An individual’s right to contraceptive information and services is grounded in internationally recognized human rights, including:¹

- the right to life,
- the right to health,
- the right to privacy,
- the right to equality and non-discrimination,
- the right to contraceptive information and education, and
- the right to determine the number and spacing of one’s children.

The U.S. has ratified two international treaties that enshrine many of these rights: the International Covenant on Civil and Political Rights (ICCPR), which includes protections for the rights to life, equality and non-discrimination, and privacy,² and the International Convention on the Elimination of All Forms of Racial Discrimination (ICERD), which includes a duty to eliminate racial discrimination in the exercise of the right to health.³ By ratifying these treaties, the U.S. assumed an international legal obligation to respect, protect, and fulfill the rights they contain, and to create an enabling environment in which those rights can be enjoyed.⁴ The U.S. has also signed and expressed its intent to abide by several additional treaties that not only include many of these same protections, but also provide protections for the right to contraceptive information and education and the right to determine the number and spacing of one’s children.⁵

A survey of ministries of health and other technical experts in 150 countries confirmed that birth control pills are available over the counter in most of those places, either formally by law or informally in practice.⁶ While a handful of countries require a health screening before consumers may purchase birth control over the counter, most do not. The results of the survey are available in an interactive map on the OCs OTC Working Group’s website: ocsotc.org.

IV. Leader of the Pack: the Progestin-Only Pill

There are two broad categories of birth control pills: Combined Oral Contraceptives (COCs), which contain estrogen and progestin, and Progestin-only Pills (POPs). There is only one formulation of a POP currently registered and available in the United States: norethindrone. Available as a generic or marketed under brand names such as *Micronor* and *Nor-QD*, this type of pill is commonly known as the “mini pill.” Another formulation, norgestrel (marketed as *Ovrette*), is registered in the U.S. but is not currently available on the market.

Although POPs are frequently prescribed for breastfeeding women and individuals with contraindications for COCs, currently they are only used by about 4% of people taking birth control pills in the United States.²⁵ The vast majority of women taking birth control pills rely on COCs.

Research suggests that both COCs and POPs meet the FDA’s criteria for OTC sales:²⁶

- They are **nontoxic** in the event of an overdose.
- They are **not addictive**.
- Women can **self-diagnose** their need for birth control to avoid unintended pregnancy.
- Women can safely take the pill without consulting a clinician—research indicates women can **self-screen** for contraindications using a simple checklist.
- Women do not need a clinician’s explanation in order to take the pill as indicated; **the instructions are simple** and research suggests that continuation is similar or even higher for women who access birth control over the counter instead of at a clinic.

COCs do have some serious contraindications: the risk of blood clots, heart attack or stroke is higher for women with hypertension, women aged 35 and over who smoke, and those who suffer from migraines with aura. These risks likely contribute to some clinicians’ apprehension about OTC birth control pills. However, it is important to note that even for women with these conditions, the overall risk remains low—and pregnancy actually puts women at *higher* risk of heart attack or stroke than using COCs does.²⁷ Perhaps most importantly, research shows that women are capable of using a simple checklist to effectively self-screen for contraindications and determine if the pill is right for them.²⁸

Nonetheless, women with undiagnosed hypertension run the risk of self-screening ineffectively. In order to most effectively make the case for OTC status, the prevalence of this risk and the potential for workarounds, such as making a screening tool for high blood pressure available in the store aisle,²⁹ should be assessed.

In general, there are fewer contraindications to POPs than COCs; POP contraindications are also rarer than contraindications for COCs.³⁰ However, there are some aspects of POPs that tend to make them less desirable to many women: breakthrough bleeding is more common, and women are counseled to take POPs at the same time every day for maximum effectiveness. Nonetheless, a POP is likely to achieve OTC status first, in part because of the relative lack of contraindications. In addition, the FDA has already approved progestin-only emergency contraception for OTC status. This precedent may make the FDA predisposed to approving a POP as the first daily-use OTC birth control pill.

Overall, given their strong safety profile, both COCs and POPs appear to be strong candidates for OTC access. Ultimately, women will be best served if both types of pill are available without a prescription.

V. Just Say No: Political Age Restrictions

An OTC birth control pill has the potential to benefit women of all reproductive ages. Unfortunately, in the case of emergency contraception, key FDA officials responded to political pressure and initially imposed age restrictions for non-prescription use. As we look ahead to a prescription-to-OTC switch for birth control pills, the example of EC serves as a cautionary tale.

Some of the traditional challenges people face acquiring a prescription—such as cost, transportation, access to a health care provider, and time away from other commitments and responsibilities—are particularly likely to present barriers for young people. Moreover, the age-based regime imposed on EC created access barriers that negatively impacted consumers of *all* ages. To enforce the restrictions, the FDA required stores to keep EC behind pharmacy counters and obtain proof of age before dispensing it to a customer without a prescription. As a result, sales were limited to pharmacy counter hours, pharmacists served as gatekeepers even for those individuals eligible to purchase EC without a prescription, and individuals could be turned away if they did not have acceptable identification. Not surprisingly, confusion about the rules was common among both pharmacists and the public.



Age Requirements as Identification Barriers

Imposing an age requirement on OTC birth control would deny the benefits of OTC access not only to young people, but also to those who do not have the identification necessary to demonstrate their age to a pharmacist. This de facto ID requirement would fall hardest on women for whom an OTC pill would be especially useful, such as many immigrant women, women of color and low-income women.¹

Access to and use of EC improved as the prescription requirement and associated barriers were lifted. For example, EC sales doubled in the year after EC became available without a prescription for people 18 and older.³¹ Moreover, data suggests that increased awareness of EC and improvements in access over time have resulted in increased use by sexually active teens.³² At the same time, the data refute arguments made by opponents of OTC EC, who claimed that it would encourage more teens to become sexually active.³³

Absent evidence that adolescents cannot use OTC birth control pills properly, no age restrictions should be attached to OTC status. Unfortunately, however, a major lesson learned from the more-than-ten-year battle to bring emergency contraception over the counter is that birth control pills will likely be held to a different standard than other medication when it comes to demonstrating their safety and efficacy for young people. In order to avoid politically motivated and unnecessary age restrictions on OTC sales, pharmaceutical companies should be prepared to include adolescents in the clinical studies presented to the FDA in support of a prescription-to-OTC switch.

Moving Emergency Contraception Over the Counter

In 2001, the Center for Reproductive Rights filed a citizen petition on behalf of over 70 medical and public health organizations requesting OTC status for EC. The FDA denied the petition for the first time in 2006 and then again in 2011. Meanwhile, the manufacturer of the EC product Plan B submitted an application for OTC status in 2003. Although a panel of FDA experts reviewed the evidence and recommended approval of the manufacturer application, the FDA deviated from standard practice and rejected it a year later, suggesting that the manufacturer reapply with a proposal including an age restriction. When the FDA subsequently failed to meet its own deadline for responding to the revised application, the Center filed a federal lawsuit against the agency for ignoring science and holding Plan B to a different standard than other drugs.

Though the FDA agreed to make Plan B available over the counter in 2006, it did so only for those 18 years of age and older; anyone under the age of 18 was still required to present a prescription to purchase EC. In 2009, OTC access was extended to those 17 years of age and older after a federal district court determined the FDA's actions to be arbitrary, capricious and unreasonable. The Court also ordered the agency to reconsider the remaining restrictions on EC. After essentially ignoring this directive for another two and a half years, the FDA Commissioner finally approved OTC EC for all ages at the end of 2011—only to be blocked in an unprecedented move by then Health and Human Services (HHS) Secretary Kathleen Sebelius and publicly supported by President Obama. It took additional litigation and two more years for the FDA to remove all age restrictions and grant EC full OTC status.

VI. The Importance of Insurance Coverage

For an OTC pill to truly improve contraceptive access, it must be affordable to those who would most benefit from the convenience of an OTC option. So far, assumptions that OTC status would result in a significantly lower price point for emergency contraception have not proven valid.³⁴ Accordingly, the biggest step policymakers can take to lay the groundwork for an OTC pill is to ensure that insurance coverage of OTC birth control products does not hinge on a prescription requirement.

As noted in the introduction, the ACA contraceptive coverage benefit requires most private insurance plans to cover birth control for women without imposing cost sharing (such as copays or deductibles). This policy was established by the Health Resources and Services Administration (HRSA), an agency under the Department of Health and Human Resources (HHS), as part of the Women's Preventive Services Guidelines. It is based on a recommendation from the Institute of Medicine (IOM) that coverage include "the full range of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity."³⁵ On its face, the scope of this recommendation includes birth control methods that are available over the counter, such as EC, female condoms, sponges, and spermicide.

Nonetheless, when HRSA issued the guidelines, they included the instruction that birth control coverage must be provided "as prescribed." While this could be interpreted in different ways, HHS has subsequently indicated that insurers may require a prescription from a health care provider as a prerequisite to obtaining no-cost coverage for birth control products.³⁶

Obviously, if a woman first has to get a prescription from her provider in order for an OTC pill to be covered by her insurance, she loses the benefits of OTC access. Ensuring that the ACA contraceptive coverage benefit extends to OTC products without requiring a prescription is a critical policy change that will lay the groundwork for comprehensive OTC access. In a 2015 committee opinion, ACOG affirmed its support for “over-the-counter access to oral contraceptives with accompanying full insurance coverage or cost supports.”³⁷

This policy change could be achieved legislatively. A federal bill introduced in the 114th Congress by Sen. Patty Murray (D-WA) (S.1532) and Reps. Tammy Duckworth (D-IL), Patrick Murphy (D-FL), and Joe Crowley (D-NY) (H.R.3163) called the “Affordability Is Access Act” would extend private insurance coverage under the ACA to an OTC birth control pill purchased without a prescription. However, congressional action is not required to effect this change; HRSA could revise the current policy that allows insurers to require a prescription as a prerequisite to no cost coverage. In October 2015, HRSA announced its intention to update the guidelines by the end of 2016.³⁸

Changing this policy would have immediate benefits for women around the country who need birth control methods that are currently available over the counter, including EC, while also setting the stage for comprehensive access to an OTC birth control pill. In the meantime, incremental change is also possible. Under the existing policy, insurers may opt to cover OTC birth control products without requiring a prescription and, in response to prompts from advocates, at least three private insurers have adopted this more expansive policy.³⁹

Public Insurance Coverage

Public insurance coverage for an OTC pill is also essential. The challenges inherent in obtaining a prescription for birth control can be especially difficult to overcome for low-income individuals. Medicaid is currently the single largest source of funding for family planning services in the United States.¹ With over 13 million women ages 15-49 enrolled in the program,² coverage of OTC birth control products will help ensure that they serve as a viable option for low-income women and families.

Several state Medicaid programs already cover OTC family planning products, such as condoms and EC, without a prescription. The Indian Health Service and the U.S. military’s TRICARE insurance program also cover EC without a prescription. These examples demonstrate that technical barriers to covering OTC products are surmountable and provide models for the remaining federal and state programs to follow.

VII. Contraceptive Access in the States: Emerging Trends

The FDA must take action for a birth control pill (or any drug) to become available over the counter; policymakers cannot bestow OTC status on medication. Nonetheless, two emerging state legislative trends have the potential to expand contraceptive access by mitigating some of the barriers posed by traditional prescription and insurance regimes.

Pharmacy Access Models

California and Oregon have both adopted laws authorizing versions of a “pharmacy access model” that permits pharmacists to prescribe and dispense birth control on the spot; Oregon’s law went into effect in January 2016 and California is expected to implement its law in March 2016. Several additional states are likewise considering similar models so far in 2016, including Missouri, New York, South Carolina and Tennessee.

State approaches to pharmacy access can differ in important ways, as exemplified by the models now in place in California and Oregon. Pharmacists in California are authorized to prescribe a range of self-administered hormonal contraceptives to women of any age, including birth control pills, the contraceptive patch, the vaginal ring, and the birth control shot.⁴⁰ In Oregon, on the other hand, pharmacy access is limited to birth control pills and the contraceptive patch.⁴¹ Moreover, until 2020, women under 18 may only access birth control from a pharmacist in Oregon if they have a record of a previous prescription from a primary care provider or a women’s health care provider.⁴²

In general, the pharmacy access model has the potential to greatly expand access to contraception by eliminating a separate trip to a primary health care provider to get a prescription. Because interaction with a pharmacist and a quick health screening are typically required, people who feel concerned about eliminating clinician counseling may feel more comfortable with this approach.

At the same time, pharmacy access is not a substitute for full, nationwide OTC status. It is a state-by-state approach without encouraging prospects for adoption in many states. In addition, there are a number of limitations that can stem from requiring pharmacist involvement. For one, access remains dependent on the location of a pharmacy counter and its business hours, which may be shorter than that of the store in which it is located. In addition, if insurers do not adequately reimburse pharmacists for the time they spend counseling and screening women, pharmacists may not be able to devote time to providing birth control, or additional costs may be passed on to consumers. Finally, interposing a pharmacist as a gatekeeper in place of a primary care provider is unnecessary for products that are safe and effective for OTC use, and could be detrimental if a pharmacist objects to prescribing birth control for personal rather than medical reasons.

Insurance Coverage for a Twelve-Month Supply

Another promising trend at the state level promotes access to contraception by requiring insurers to cover a 12-month supply of birth control pills at one time. Oregon and Washington, D.C. passed laws to this effect in 2015 and similar legislation is under consideration in eight states as of February 2016. By making it affordable for women to take home enough birth control to last up to a year, policies like these eliminate the need for routine trips to a pharmacy and can help prevent gaps in birth control use.⁴³

Looking ahead to an OTC pill, coverage of a year-long supply would help ensure more women have the ability to access and continue using a convenient, effective method of birth control. At the federal

level, HHS could take administrative action to build this policy into the ACA birth control benefit. In July 2015, Representatives Jackie Speier (D-CA), Suzanne Bonamici (D-OR) and 53 of their colleagues in the House of Representatives sent a letter to HHS Secretary Sylvia Burwell requesting the Department issue guidance requiring insurers to cover a year-long supply of birth control without cost-sharing.⁴⁴

VIII. Playing Politics at the Federal Level

Support for OTC birth control emerged as a political talking point in a number of key congressional races in 2014.⁴⁵ Bipartisan support for an OTC pill is a promising development. In many cases, however, conservative politicians have offered their support for OTC birth control as an alternative to the ACA birth control benefit and other policies aimed at improving access to reproductive health care. For example, in his race against then-incumbent Mark Udall of Colorado, now Senator Cory Gardner (R-CO) deflected criticism of his poor record on access to contraception, including his opposition to the ACA and the birth control benefit, by proclaiming support for OTC birth control. Once in office, he followed up on this position by partnering with Sen. Kelly Ayotte (R-NH) to introduce a bill related to OTC access.

The next big step for birth control in the U.S. is to make it available:

- ✓ *without a prescription nationwide,*
- ✓ *to all ages, and*
- ✓ *with comprehensive insurance coverage.*

Introduced in 2015, Senate Bill 1438 would make the prescription-to-OTC switch more attractive to pharmaceutical companies by requiring the FDA to waive the filing fee and grant priority review status to their applications. The focus of the bill is therefore on mandating changes to the FDA's typical regulatory process. Two additional aspects of the proposal also suggest that it is not a genuine attempt to expand access to contraception for the people most likely to benefit from an OTC option. First, the bill would impose a politically motivated age

restriction by making incentives available only to companies that seek to limit OTC access to individuals 18 and older. Second, it is silent on the issue of insurance coverage, the one area of federal policy that Congress could improve to lay the groundwork for OTC birth control. Instead, the bill proposes a policy change that would allow individuals with Health Savings Accounts and Flexible Spending Accounts to pay for an OTC birth control pill with money that is set aside pre-tax; this is a poor substitute for insurance coverage, especially for the many women who are unable to set aside money from their paycheck in anticipation of birth control costs.

In contrast, the Affordability Is Access Act (see page 10) would lay the groundwork for an OTC birth control pill by including it within the scope of the ACA birth control benefit—ensuring that most women with private insurance coverage would be able to use their insurance to purchase the product without any out-of-pocket costs. The bill would also protect consumers from interference by retailers that object to providing OTC birth control. These are critical first steps toward ensuring access to an OTC pill.

Nonetheless, the necessary work to pave the way for affordable OTC birth control does not end with the Affordability Is Access Act. One critical policy change that would have an immediate impact is to ensure that the ACA birth control benefit extends to all OTC methods, including those that are currently available over the counter such as emergency contraception, condoms, sponges and

spermicide. In addition, steps must also be taken to ensure that no-cost coverage extends to the millions of women who access birth control through public programs and that protections are in place to ensure that third parties, such as employers, are not able to discriminate against women by denying birth control coverage.

IX. Conclusion

OTC status is the next big step when it comes to expanding access to contraception and reducing unintended pregnancy in the U.S. Though a progestin-only pill is the likely first candidate for OTC status, the available data suggest that combined hormonal pills are also appropriate for OTC use. Support for OTC access is widespread among medical, public health, and reproductive health, rights, and justice groups and practitioners.⁴⁶

In order to effect change in a meaningful way for the women most likely to benefit from an OTC pill—including young women, women of color and low-income women—it must be covered by insurance and available without politically motivated age restrictions.

Access to contraception is grounded in international human rights. It is incumbent upon policymakers in the U.S. to take affirmative steps to remove the obstacles—such as prescription requirements and cost barriers—that prevent Americans from realizing these rights.

Endnotes

- ¹ The Administration has clarified that coverage of sex-specific preventive services cannot be limited based on an individual's sex assigned at birth, gender identity, or recorded gender. U.S. DEP'T OF HEALTH & HUMAN SERVICES, U.S. DEP'T OF LABOR, U.S. DEP'T OF THE TREASURY, FAQs ABOUT AFFORDABLE CARE ACT IMPLEMENTATION (PART XXVI) (2015) (Question 5), *available at* <http://www.dol.gov/ebsa/faqs/faq-aca26.html>.
- ² AMY BURKE & ADELLE SIMMONS, OFFICE OF THE ASSISTANT SEC'Y FOR PLANNING AND EVALUATION, U.S. DEP'T OF HEALTH & HUMAN SERVICES, INCREASED COVERAGE OF PREVENTIVE SERVICES, WITH ZERO COST SHARING UNDER THE AFFORDABLE CARE ACT 1 (2014), *available at* https://aspe.hhs.gov/sites/default/files/pdf/76901/ib_PreventiveServices.pdf.
- ³ *Id.* at 5.
- ⁴ A 2014 national survey found that 69% of adults support requiring health plans to cover birth control. Support is even higher among women, black and Hispanic individuals, parents with children under 18, and adults that already have insurance. Press Release, Univ. of Michigan, More than two-thirds of Americans Support Mandated Coverage of Birth Control in Health Plans (April 24, 2014), *available at* <http://www.uofmhealth.org/news/archive/201404/more-two-thirds-americans-support-mandated-coverage-birth>.
- ⁵ GUTTMACHER INSTITUTE, UNINTENDED PREGNANCY IN THE UNITED STATES (July 2015), *available at* <https://www.guttmacher.org/pubs/FB-Unintended-Pregnancy-US.html>.
- ⁶ For more information, see the OCs OTC Working Group's website at www.ocsotc.org.
- ⁷ See OCs OTC Working Group Resources, http://ocsotc.org/?page_id=3.
- ⁸ See Free the Pill Home Page, www.freethepill.org.
- ⁹ Emily Ekins, *Poll: 70% Favor Legalizing Over-the-Counter Birth Control*, REASON.COM, Oct. 20, 2014, <https://reason.com/blog/2014/10/20/poll-70-favor-legalizing-over-the-count2>. For a summary of relevant research and polling on public interest, see BRITT WAHLIN, KATE GRINDLAY, DANIEL GROSSMAN, SHOULD ORAL CONTRACEPTIVES BE AVAILABLE OVER THE COUNTER? 6-7 (Food and Drug Law Institute Policy Forum) (2014), *available at* http://www.ibisreproductivehealth.org/sites/default/files/files/publications/Wahlin%20B%20%20FDLI%20Policy%20Forum%20Should%20OC%20be%20available%20OTC%2003_14_14.pdf. See also OCs OTC Working Group, Resources ("Public Opinion Surveys"), http://ocsotc.org/?page_id=3#public.
- ¹⁰ Daniel Grossman et al., *Interest in Over-the-Counter Access to Oral Contraceptives among Women in the United States*, 88 CONTRACEPTION 544, 548 (2013).
- ¹¹ *Id.* at 550.
- ¹² Daniel Grossman, *The Potential Impact of Over-the-Counter Access to Oral Contraceptives to Reduce Unintended Pregnancy*, 92 AM FAMILY PHYSICIAN 968 (2015); *Id.* at 548-9.
- ¹³ J.E. Potter et al., *Continuation of prescribed compared with over-the-counter oral contraceptives*, 117 Obstet Gynecol. 551 (2011), *available at* http://journals.lww.com/greenjournal/Fulltext/2011/03000/Continuation_of_Prescribed_Compared_With.6.aspx.
- ¹⁴ Grossman et al., *supra* note 10, at 550.
- ¹⁵ Kate Grindlay & Daniel Grossman, *Prescription Birth Control Access Among U.S. Women at Risk of Unintended Pregnancy*, J. OF WOMEN'S HEALTH 1, 2 (2016) (published online ahead of print), *available at* <http://online.liebertpub.com/doi/pdfplus/10.1089/jwh.2015.5312>.
- ¹⁶ *Id.* at 2-3.
- ¹⁷ *Committee Opinion: Over-the-Counter Access to Oral Contraception*, AM. COLL. OF OBSTETRICIANS AND GYNECOLOGISTS 544 (Dec. 2012) (reaffirmed 2014), *available at* <http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Over-the-Counter-Access-to-Oral-Contraceptives>; *Committee Opinion: Access to Contraception*, AM. COLL. OF OBSTETRICIANS AND GYNECOLOGISTS 615 (Jan. 2015), *available at* <http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Access-to-Contraception>.

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- ¹⁸ *Resolution: Over-the-Counter Oral Contraceptives*, AM. ACAD. OF FAMILY PHYSICIANS (July 2014), available at <http://www.aafp.org/about/policies/all/otc-oral-contraceptives.html>.
- ¹⁹ *D-75.995, Over-the-Counter Access to Oral Contraceptives*, AM. MED. ASSOC., available at <https://www.ama-assn.org/ssl3/ecom/PolicyFinderForm.pl?site=www.ama-assn.org&uri=%2Fresources%2Fhtml%2FPolicyFinder%2Fpolicyfiles%2FDIR%2FD-75.995.HTM>.
- ²⁰ J. McIntosh et al., *Changing oral contraceptives from prescription to over-the-counter status: An opinion statement of the Women's Health Practice and Research Network of the American College of Clinical Pharmacy*, 31 PHARMACOTHERAPY 424 (2011).
- ²¹ OCs OTC Working Group, Statement of Principles, http://ocsotc.org/?page_id=5.
- ²² See WAHLIN et al., *supra* note 9, at 7-8.
- ²³ See, e.g., K. White et al., *Contraindications to Progestin-Only Oral Contraceptive Pills among Reproductive Aged Women*, 86 CONTRACEPTION 199, 202 (2012); Daniel Grossman et al., *Accuracy of self-screening for contraindications to combined oral contraceptive use*, 112 J. OBSTETRICS & GYNECOLOGY 572 (2008).
- ²⁴ Kristine Hopkins et al., *Reproductive health preventive screening among clinic vs. over-the-counter oral contraceptive users*, 86 CONTRACEPTION 376 (2012).
- ²⁵ WAHLIN et al., *supra* note 9, at 5.
- ²⁶ *Id.* at 3-4; OCs OTC Working Group, Moving the birth control pill over the counter in the U.S. (July 2015), available at <http://ocsotc.org/wp-content/uploads/2015/07/OCs-OTC-Intro-Fact-Sheet-Brief-Final.pdf>.
- ²⁷ WAHLIN et al., *supra* note 9, at 5.
- ²⁸ Daniel Grossman et al., *supra* note 23.
- ²⁹ There is a growing interest in using technology to help promote appropriate screening and use of OTC medications, including at the FDA, which created the Nonprescription Safe Use Regulatory Expansion (NSURE) task force in 2012 “to evaluate new strategies for converting prescription-only drugs to OTC medications.” See, Michael R. Page, *Rx-to-OTC Switches: Trends to Watch*, PHARMACY TIMES, Feb. 9, 2015, <http://www.pharmacytimes.com/publications/issue/2015/february2015/rx-to-otc-switches-trends-to-watch/p-2>.
- ³⁰ K. White et al., *supra* note 23.
- ³¹ Rob Stein, *Plan B Use Surges, and So Does Controversy*, WASH. POST, July 7, 2007, <http://www.washingtonpost.com/wp-dyn/content/article/2007/07/12/AR2007071202146.html>
- ³² Ever-use of EC by females aged 15-19 increased from 8% to 22% between 2002 and 2013. CENTERS FOR DISEASE CONTROL AND PREVENTION, SEXUAL ACTIVITY, CONTRACEPTIVE USE, AND CHILDBEARING OF TEENAGERS AGED 15-19 IN THE UNITED STATES 4 (2015), available at <http://www.cdc.gov/nchs/data/databriefs/db209.htm#method>. However, because EC only became available without a prescription for all ages in the middle of 2013, this increase cannot be attributed solely to OTC status.
- ³³ While ever-use of EC by females aged 15-18 increased between 2002 and 2013, the number of sexually active teens remained steady. *Id.*
- ³⁴ AMERICAN SOCIETY FOR EMERGENCY CONTRACEPTION, INCHING TOWARDS PROGRESS: ASEC'S 2015 PHARMACY ACCESS STUDY (2015), available at http://americansocietyforec.org/uploads/3/2/7/0/3270267/asec_2015_ec_access_report_1.pdf.
- ³⁵ INSTITUTE OF MEDICINE, CLINICAL PREVENTIVE SERVICES FOR WOMEN: CLOSING THE GAPS 109-110 (National Academics Press) (2011), available at <http://www.nap.edu/catalog/13181/clinical-preventive-services-for-women-closing-the-gaps>.
- ³⁶ U.S. DEP'T OF HEALTH & HUMAN SERVICES, U.S. DEP'T OF LABOR, U.S. DEP'T OF THE TREASURY, FAQs ABOUT AFFORDABLE CARE ACT IMPLEMENTATION PART XII (Feb. 20, 2013) (Question 15), available at <http://www.dol.gov/ebsa/faqs/faq-aca12.html>.
- ³⁷ AM. COLL. OF OBSTETRICIANS AND GYNECOLOGISTS Committee Opinion 615, *supra* note 17.
- ³⁸ In October 2015, HRSA announced a funding opportunity for an organization to “improve adult women’s health across the lifespan by engaging a coalition of health professional organizations to recommend updates to the HRSA supported Women’s Preventive Services Guidelines.” As noted by HRSA, “[t]he IOM, as part of its report, recommended that HHS periodically update the review of women’s preventive services through the establishment of an independent commission.” HRSA also noted that an IOM-recommended five year benchmark for updating would be met if the project is completed by the end of 2016. HEALTH

RESOURCES AND SERVICES ADMINISTRATION, U.S. DEP'T OF HEALTH & HUMAN SERVICES, GUIDELINES FOR WOMEN'S PREVENTIVE SERVICES, FUNDING OPPORTUNITY ANNOUNCEMENT 2-3 (2015), *available at* https://grants.hrsa.gov/2010/Web2External/Platform/Interface/DisplayAttachment.aspx?dm_rtc=16&dm_attid=332cb922-06c0-436e-a735-ca7e388ded37&dm_attinst=0.

- ³⁹ Email from Britt Wahlin, vice president for development and public affairs, Ibis Reproductive Health, to Megan Donovan, federal policy counsel, Center for Reproductive Rights (Feb. 8, 2016) (on file with author).
- ⁴⁰ Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraception, Cal. Dep't of Consumer Affairs Board of Pharmacy, Proposed Regulation, http://www.pharmacy.ca.gov/laws_regs/1746_1_pt.pdf.
- ⁴¹ See Oregon State Pharmacy Association, Oregon Pharmacists Tasked to Improve Access to Hormonal Birth Control FAQs, <http://www.oregonpharmacy.org/hb2879---hormonal-birth-control-faqs>.
- ⁴² *Id.*
- ⁴³ Diana Greene Foster et al., *Number of oral contraceptive pill packages dispensed and subsequent unintended pregnancies*, 117 J. OBSTETRICS & GYNECOLOGY 566 (2011).
- ⁴⁴ Jackie Speier et al, Letter to the Honorable Sylvia Burwell (July 2, 2015), <http://bonamici.house.gov/sites/bonamici.house.gov/files/7-2-15%20Congressional%20Letter%20to%20HHS%20re%2012%20mo%20bc%20dispensing.pdf>.
- ⁴⁵ See, e.g., Mara Liasson, *Changing Tack, GOP Candidates Support Over-the-Counter Birth Control*, NPR, Sept. 12, 2014, <http://www.npr.org/sections/health-shots/2014/09/12/347749930/changing-tack-gop-candidates-support-better-access-to-birth-control>; Sandhya Somashekhar, *GOP Senate Hopefuls Favor Over-the-Counter Birth Control*, WASH. POST, Sept. 2, 2014, https://www.washingtonpost.com/national/health-science/gop-senate-hopefuls-favor-over-the-counter-birth-control/2014/09/02/1916bef2-32c0-11e4-a723-fa3895a25d02_story.html. See also Sneha Barot, *Moving Oral Contraceptives to Over-the-Counter Status: Policy Versus Politics*, 18 GUTTMACHER POLICY REVIEW 85 (2015), *available at* <http://www.guttmacher.org/pubs/gpr/18/4/gpr1808515.pdf>.
- ⁴⁶ For a list of organization that endorse the OCs OTC Working Group's Statement of Purpose, see http://ocsotc.org/?page_id=5.

Endnotes for Boxes

The Border Contraceptive Access Study

- ¹ See Population Research Center, University of Texas at Austin, Border Contraceptive Access Study, <http://www.prc.utexas.edu/bcas/index.html> (last visited Feb. 15, 2016).
- ² Joseph E. Potter et al., *Clinic Versus Over-the Counter Access to Oral Contraception: Choices Women Make Along the US-Mexico Border*, 100 AM. J. PUB. HEALTH 1130, 1134 (2010).

Making the Case: Human Rights and Global Context

- ¹ For more analysis of the international human rights treaties and standards that protect the right to contraceptive information and services, see CTR. FOR REPRODUCTIVE RIGHTS & UNITED NATIONS POPULATION FUND, THE RIGHT TO CONTRACEPTIVE INFORMATION AND SERVICES FOR WOMEN AND ADOLESCENTS 2010 [hereinafter CRR & UNFPA], *available at* <http://www.reproductiverights.org/document/briefing-paper-the-right-to-contraceptive-information-and-services-for-women-and-adolescent>.
- ² The United Nations Human Rights Committee (HRC), which monitors implementation of the ICCPR, has explained that equality in the exercise of the rights to life, non-discrimination, and privacy includes reproductive rights. The Committee has also expressed concern about obstacles to accessing contraception for women and has recommended that states improve access to family planning services, including contraception.
- ³ The United Nations Committee on the Elimination of Racial Discrimination (CERD), which monitors implementation of ICERD, reiterated concern in 2014 "at the persistence of racial disparities in the field of sexual and reproductive health" in the U.S. The Committee called upon the U.S. to, among other things, "[t]ake concrete measures to ensure that all individuals...have effective access to affordable and adequate health-care services" and to "eliminate racial disparities in the field of sexual and reproductive health." CERD Committee, Concluding Observations: United States, para. 15 (2014) *available at*

<http://www.state.gov/documents/organization/235644.pdf>. The Committee's recommendations echoed those provided in a report submitted to the Committee by the Center for Reproductive Rights, SisterSong Women of Color Reproductive Justice Initiative, and the National Latina Institute for Reproductive Health, REPRODUCTIVE INJUSTICE: RACIAL AND GENDER DISCRIMINATION IN U.S. HEALTH CARE 2014, *available at* http://www.reproductiverights.org/sites/crr.civicactions.net/files/documents/CERD_Shadow_US.pdf.

⁴ Human Rights Committee (HRC), *General Comment No. 31: Nature of the General Legal Obligation on States Parties to the Covenant* (18th Sess., 2004), paras. 3-6, U.N. Doc. CCPR/C/21/Rev.1/Add.13 (2004); HRC, *General Comment No. 3: Implementation at the National Level* (Art. 2), (13th Sess., 1981), para. 1; in COMPILATION OF GENERAL COMMENTS AND GENERAL RECOMMENDATIONS ADOPTED BY HUMAN RIGHTS TREATY BODIES, U.N. Doc. HRI/GEN/1/Rev.1 at 4 (1994).

⁵ The Convention on the Elimination of All Forms of Discrimination against Women (CEDAW) includes protections for the rights to health, equality and non-discrimination, contraceptive information and education, and the right to determine the number and spacing of one's children. The International Covenant on Economic, Social and Cultural Rights (ICESCR) includes protections for the rights to health and equality and non-discrimination. The Convention on the Rights of the Child (CRC) includes protections for the rights to life, health, and privacy. For more information, see CRR & UNFPA, *supra* note 1.

⁶ Kate Grindlay & Daniel Grossman, *Prescription requirements and over-the-counter access to oral contraceptives: A global review*, 88 CONTRACEPTION 91 (2013).

Age Requirements as Identification Barriers

¹ See, e.g., BRENNAN CENTER FOR JUSTICE, *CITIZENS WITHOUT PROOF: A SURVEY OF AMERICANS' POSSESSION OF DOCUMENTARY PROOF OF CITIZENSHIP AND PHOTO IDENTIFICATION* (2006), http://www.brennancenter.org/sites/default/files/legacy/d/download_file_39242.pdf (finding that millions of Americans do not have government-issued photo identification and certain groups, including the poor and minority citizens, are less likely to possess such documentation than the general population).

Public Insurance Coverage

¹ USHA RANJI, HENRY J. KAISER FAMILY FOUNDATION, *MEDICAID AND FAMILY PLANNING: BACKGROUND AND IMPLICATIONS OF THE ACA 1* (2016) *available at* <http://files.kff.org/attachment/issue-brief-medicaid-and-family-planning-background-and-implications-of-the-aca>.

² *Id.* at 2.

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