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Should Oral Contraceptives Be Available  
Over the Counter?

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# Should Oral Contraceptives Be Available Over the Counter?

## I. INTRODUCTION

Oral contraceptives (OCs), popularly known as the birth control pill, have been on the U.S. market for over 50 years and used by more than 80% of sexually active American women, making them women's top contraceptive choice.<sup>1</sup> But while in over 100 countries OCs are available over the counter or from a pharmacist, in the United States OCs are available by prescription only,<sup>2</sup> which may limit women's access to this safe and highly effective contraceptive method. Nearly 50% of pregnancies are unintended in the United States<sup>3</sup>— one of the highest rates in the developed world<sup>4</sup>— and research shows that the prescription may be a barrier to women's access to and consistent use of OCs. Moving OCs over the counter (OTC) in the United States could help more women obtain their method of choice and reduce unintended pregnancy. The most likely pathway for moving an OC product OTC would be an application submitted by a pharmaceutical company to the Food and Drug Administration (FDA) for a prescription-to-OTC switch of one OC formulation.

The primary issues raised by the question of moving OCs OTC include whether it is safe for women to access OCs OTC and whether they meet the FDA criteria; whether women are interested in obtaining OCs OTC; and whether an OTC OC would be affordable as well as relevant in the new health care environment, in which most insurance plans are now required to cover the full range of FDA-approved contraceptives with no cost sharing. In addition, the opinions of physicians and other clinicians are an important consideration. In this policy brief, we will review the evidence related to OCs OTC, including safety, and women's and providers' perspectives, discuss who might benefit from the availability of an OTC OC, and address other potential concerns related to OTC availability for OCs. We will also discuss the case for an OTC progestin-only pill, which is a likely first candidate for an OTC OC.

Our analysis will show that the safety of OCs outweighs the risks of making OCs available over the counter and that women are able to use a simple checklist to determine whether they have any medical conditions that would make it unsafe for them to use OCs. In addition, over two-thirds of women support moving OCs OTC, and one-third of women not currently using a method report they would be likely to use an OTC OC.<sup>5</sup> Major professional medical associations, such as the American College of Obstetricians and Gynecologists (ACOG), also support moving OCs OTC.<sup>6</sup> But policy solutions are needed to ensure that a future OTC OC is covered by both public and private insurance plans, ideally without a prescription. In addition, the manufacturer of a future OTC OC will need to price its product affordably, keeping in mind that women will not likely pay more than \$10-20 for a single pack of OCs.<sup>7</sup>

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## POLICY RECOMMENDATIONS

We ask a pharmaceutical company to:

- Conduct the necessary research that includes adolescents to support a prescription-to-OTC switch application to the FDA.

We ask the FDA to:

- Consider the evidence, then approve an application from a manufacturer for an OTC OC pill with no age restriction.

We ask the Department of Health and Human Services (HHS) to:

- Remove “as prescribed” from the Affordable Care Act’s (ACA) preventive services rule on contraceptive coverage so that insurers are required to cover OTC contraceptive methods without requiring a prescription.

We ask the Centers for Medicare and Medicaid Services (CMS) to:

- Change federal Medicaid policy so that states are able to receive a federal match for covering OTC contraceptives without requiring women to have a prescription.

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## II. BACKGROUND

Women spend approximately five years of their lives trying to become pregnant, being pregnant, and postpartum, and 30 years trying to prevent pregnancy.<sup>8</sup> Ninety-nine percent of women use contraception at some point in their lives.<sup>9</sup> But still half of all pregnancies in the United States are unintended.<sup>10</sup> Among those, an estimated 5% are due to contraceptive failure, 43% to inconsistent or incorrect use, and 52% to gaps in use of at least one month or to non-use.<sup>11</sup> These gaps in use and non-use can result when women experience barriers accessing contraception.<sup>12</sup> In addition, low-income women and women of color are more likely to face barriers accessing contraception<sup>13</sup> and are at higher risk of unintended pregnancy.<sup>14</sup>

Moving OCs OTC has been suggested as one strategy for reducing unintended pregnancy and giving women more autonomy and control over their reproductive lives. Currently in the United States, a woman must have a prescription from her health care provider in order to access OCs; for some women the prescription is a barrier.

OCs, popularly known as the birth control pill, are used by 82% of American women at some point in their lives<sup>1</sup> and are the top choice for contraception.<sup>15</sup> Nine percent of women using OCs experience an unintended pregnancy in the first year of typical use, compared to 18% of women

using male condoms.<sup>16</sup> First approved by the FDA in 1960, the pill revolutionized women's lives and society as we know it. It has been attributed to numerous economic and social gains for women and families, including helping women achieve near parity in the workplace.<sup>17</sup> Since the first product was introduced in 1960, dozens of formulations and brand names as well as generic products have entered the global market.

Oral contraceptives are also one of the best studied medicines on the market today. Soon after the pill was introduced in the United States, women began reporting problems that were later attributed to the high dosages of hormones in the early products. Women rose up and demanded to be informed of potential dangers and side effects from using the pill, launching the women's health movement. Soon after, pills with lower hormone dosages were introduced and pill packages began to include a patient information sheet.<sup>18</sup> We now have over 50 years of research documenting the safety and efficacy of the pill, as well as evidence on non-contraceptive benefits including reductions in pain and heavy bleeding during menstruation, acne, ectopic pregnancy, iron-deficiency anemia, pelvic inflammatory disease requiring hospitalization, endometrial cancers, and benign breast disease, among others.<sup>19</sup> An editorial in *The Lancet* argued that the pill should be made more widely available through OTC access because they are the only proven ovarian cancer prevention strategy; the editorial cites data showing that in the last 50 years 200,000 cases of ovarian cancer and 100,000 deaths from the disease worldwide have been prevented through the use of OCs.<sup>20</sup>

In most of the world OCs are available either formally or informally over the counter. A 2012 study found that among 147 countries surveyed, OCs were informally available without prescription in 38% of countries, legally available without prescription (with no screening by a health professional required) in 24% of countries, legally available without prescription (screening required) in 8% of countries, and available only by prescription in 31% of countries.<sup>21</sup> In the United States, a woman must get a prescription from her health care provider to obtain OCs. Even though under the ACA most women should be able to see their provider for contraception with no cost sharing,<sup>22</sup> a woman may still incur other out-of-pocket costs, such as those related to transportation, time off work, and child care. Even a woman who has no problem seeing her provider to get a prescription may potentially face challenges due to the pill's prescription-only status. If she forgets to bring her pills on vacation or a work trip or runs out of them on the weekend, she may put herself at risk of unintended pregnancy.

OCs meet all of the FDA's criteria for over-the-counter sale.<sup>23</sup>

1. They have no toxicity in the event of an overdose.
2. They are not addictive.
3. A woman can determine on her own if use of the pill is appropriate for her. (She knows if she is at risk of unintended pregnancy).

4. A woman can take the medication as indicated without a doctor's explanation. (The instructions are simple: Take one every day).
5. A woman can take the pill safely without a provider's screening. (Research suggests that women can use a simple checklist to determine if she has any medical conditions that would make using the pill unsafe for her).<sup>24</sup>

In addition to the high unintended pregnancy rate, we know that current contraceptive offerings are not meeting women's needs. In a survey of abortion patients on desired features of contraceptives, no method on the market contained all of the features that were considered important to women in a method. But an OTC OC had 71% of the features the women surveyed found important, such as the method being easy to get, having a health benefit, and being very effective at preventing pregnancy.<sup>25</sup> According to a nationally representative survey conducted in 2011, over two-thirds of U.S. women at risk of unintended pregnancy support OTC access to OCs.<sup>26</sup> Moving OCs over the counter would provide another important option for the millions of U.S. women trying to avoid pregnancy.

### III. MAJOR POLICY ISSUES IN DISPUTE

Women who are seeking to prevent pregnancy need more options for accessing and using contraception. Removing the prescription requirement for at least one OC formulation would make it easier for women to obtain a highly effective and popular contraceptive method. Widespread use of the product could help reduce unintended pregnancy, leading to improved health outcomes for women and children and significant savings to health systems. But is moving OCs OTC a safe and feasible option?

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The major issues at hand include:

- **Would an OTC OC be safe for women?** As previously discussed, OCs meet the following criteria established by the FDA for OTC sale: OCs are non-toxic, non-addictive, have simple-to-follow instructions, and clear indications for use (a woman knows if she is at risk of unintended pregnancy). Research suggests that the final criteria — a woman's ability to determine whether OCs are safe for her to use without a physician's screening — is also met, and will be discussed further in this brief.
- **Are women interested in accessing OCs OTC?** Pharmaceutical companies need to know whether it makes sense to invest in the research and development necessary to put forward a switch application to the FDA, and how much women would be willing to pay out of pocket for an OTC OC product.
- **Do health care providers support making OCs available OTC?** Health care providers and professional medical associations are important



stakeholders in the decision to move OCs OTC since currently a woman must have an office visit in order to initiate, and often to get refills for, OCs. This brief will discuss provider support for moving OCs OTC, as well as concerns, such as the concern that women would no longer see their health care provider for their annual well-woman visits and screenings if they could access OCs without a prescription.

- **Would an OTC OC be relevant in the new health care environment?**

Under the ACA, most private insurance plans are required to cover the full range of FDA-approved contraceptives, including OTC methods, without cost sharing. The rule specifically states that insurers can require women to have a prescription to get this coverage.<sup>27</sup> This would make the OTC benefit moot for a woman who wants to use her insurance for an OTC OC product. This brief will explore why moving at least some formulations of OCs OTC still makes sense from a policy perspective, given this mandate, and will also discuss the need for policy solutions to ensure that women can use their insurance for OCs OTC without a prescription.

## IV. RESEARCH & RESPONSE TO ISSUES

### A. Would an OTC OC be safe for women?

OCs have a strong safety profile, even compared to currently available OTC medications. A user cannot overdose on them due to toxicity, they are not addictive, and side effects are not harmful.<sup>28</sup> However, they do have some contraindications. Women with hypertension, those aged 35 and over who smoke, and women who have migraines with aura have a higher risk of heart attack or stroke if they use combined oral contraceptives (COCs), which contain estrogen.<sup>29</sup> But even for these groups of women, the risks of negative outcomes are low. In addition, pregnancy puts women at higher risk for heart attack and stroke than use of COCs.<sup>30</sup> Progestin-only pills (POPs) are a formulation of oral contraceptives that do not have estrogen. Women who are contraindicated to using COCs due to hypertension can safely use POPs, and very few women have medical conditions which would make it unsafe for them to use POPs.<sup>31</sup> Contraindications for POPs include taking medications for tuberculosis or seizures, and having a history of liver disease or breast cancer.<sup>32</sup> Currently, POPs comprise just 4% of the U.S. market share for OCs, and are mostly used by women who are breastfeeding (as the estrogen in COCs may inhibit milk production in breastfeeding mothers) or who are contraindicated to COC use.<sup>33</sup>

The Border Contraceptive Access Study was a five-year, National Institutes of Health-funded study that collected data from women living along the U.S.-Mexico border who obtained their pills directly from a pharmacy in Mexico and compared them to those who obtained their pills from a clinic in El Paso, Texas. The study found that women who obtained pills OTC in Mexico were slightly more likely to have contraindications to using the pill than women who obtained them from a clinic. 13.4% of OTC users, compared to 8.6% of clinic users, were found to have at least one relative contraindication (that is, a condition that makes use of an OC risky, though benefits of use might outweigh these risks). In terms of absolute contraindications, or conditions under which OCs

should not at all be used, there was no significant difference in prevalence between OTC and clinic users (7.4% and 5.3%, respectively).<sup>34</sup> Only about 1% of women obtaining OCs OTC in pharmacies or in clinics in the Border Contraceptive Access Study had a contraindication to POPs.<sup>35</sup>

Research has also found that women can use a simple checklist to determine if they are eligible to use OCs without undergoing a medical assessment,<sup>36</sup> although one study found older women were more likely to have unrecognized hypertension.<sup>37</sup> In this latter study, which took place in El Paso, TX, a sample of 1,271 English- or Spanish-speaking women aged 18-49 were asked to use a simple 15-item checklist to self-screen for contraindications to COC use. Immediately after completing the checklist, participants had their blood pressure checked and were evaluated by a nurse practitioner to determine their eligibility for COC use. The women in the sample were, on average, in their early 30s and 92% were Latina. Participants were slightly more likely to think that they were ineligible when it was actually safe for them to use OCs than to miss a medical reason and incorrectly deem OCs safe for their use. Only 6.6% of women incorrectly thought they were appropriate for the pill when they were not. Younger and more educated women, as well as Spanish speakers, were more accurate at self-screening than other women.<sup>38</sup>

Moreover, evidence shows that OTC access to the pill may help improve continuation. In the Border Contraceptive Access Study, women who obtained OCs OTC in Mexico were found to have a significantly lower discontinuation rate than those who obtained pills in a U.S. clinic.<sup>39</sup> Research in Kuwait, where OCs are available OTC, found that continuation was no different between women who consulted with a physician and those who did not.<sup>40</sup>

Taken together it seems that the benefits of making OCs available OTC outweigh the risks, and it is important to keep in mind that for a woman with hypertension who does not wish to become pregnant, an unintended pregnancy would be riskier than using COCs, although there are other contraceptive methods that would be safer for her. In addition, provider screening is not always accurate and, as seen in the Border Contraceptive Access Study results, women who are contraindicated to COCs sometimes are still prescribed them by their health care provider.<sup>41</sup> However, because fewer women have medical conditions that make using POPs unsafe, POPs are a likely first candidate for an OTC OC product in the United States. In addition, FDA has already approved a progestin-containing product for OTC sale—levonorgestrel emergency contraception (EC)—and may look more favorably upon an application for an OTC POP. But this does not mean that the idea of moving a COC OTC should be abandoned. Concerns about women with undiagnosed hypertension using an OTC COC could be addressed by placing kiosks at pharmacies where women could check their blood pressure before purchasing COCs.

## **B. Are women interested in accessing OCs OTC?**

Recent surveys as well as research on U.S. women's desired features of contraceptives show resounding support for moving OCs OTC, with convenience being one of the main drivers of contraceptive choice. In a 2011 nationally representative survey of 2,046 U.S. women at risk of unintended pregnancy, 62% were somewhat or strongly in favor of an OTC switch for OCs. In addition, 37% said they were likely to use an OTC OC, which translates into a potential market of 11 million

adult women. Thirty-three percent of women currently using a less effective birth control method (like condoms alone) and 28% of women using no method said they were very or somewhat likely to start using the pill if it were available over the counter.<sup>42</sup> Another survey conducted in 2011 among women seeking abortion at six U.S. clinics found that 47% of respondents aged 15-17 and 62% of those aged 18-19 reported being likely to use an OTC OC if it were available; overall, 60% reported being likely to use an OTC OC if it were available.<sup>43</sup> This high proportion of adolescents interested in OTC OC use, along with the fact that young women are unlikely to have medical contraindications to the pill,<sup>44</sup> should motivate pharmaceutical companies to include adolescents in future research that will be reviewed by the FDA, such as label comprehension and actual use studies for a proposed OTC OC. Also, in a 2004 national survey of 811 U.S. women aged 18-44 which explored women's interest in pharmacy access to hormonal contraceptive methods, 68% reported they would start the pill, patch, or vaginal ring if it were available directly in a pharmacy. Though this survey focused on pharmacy access, which is different from true OTC access because pharmacist screening is required, not needing a prescription was one of the main reasons women said they supported pharmacy access. In fact, 56% of African American/Black women said they chose their current method because it did not require a prescription, compared to 51% of White women and 54% of Latinas.<sup>45</sup> And according to a recent survey of abortion patients on desired features of contraceptives, an OTC OC had 71% of the features the women found important, such as the method being easy to get, having a health benefit, and being very effective at preventing pregnancy.<sup>46</sup>

The Border Contraceptive Access Study took advantage of the natural experiment of U.S. women who obtain OCs OTC in Mexico to explore reasons women choose to access their pills OTC instead of at a clinic. The study found that women enjoy the convenience of obtaining OCs OTC and did so because they could avoid a doctor's visit and because of the lower cost of OCs at Mexican pharmacies. Women also liked like being able to send relatives and friends to pick them up.<sup>47</sup>

But an OTC OC product sold in the United States is sure to cost more than pills available in Mexican pharmacies, and cost will be an important factor for women considering obtaining an OTC OC. In the 2011 national survey, women said that they would be willing to pay up to \$20 per pack of OTC pills, which was on average about \$5 more than their current monthly out-of-pocket expenditures for contraception.<sup>48</sup>

### C. Do health care providers support making OCs available OTC?

In 2012, ACOG released a committee opinion in full support of moving OCs OTC in the United States. ACOG reviewed the evidence, weighing the risks and benefits of OTC access, and concluded that OCs should be available OTC. The committee opinion also stated that moving OCs OTC could improve women's access to contraception, which could in turn help to reduce unintended pregnancy, and noted that women are interested in obtaining OCs OTC.<sup>49</sup> In 2013, the American Medical Association adopted a resolution in support of OCs OTC. Though short of full endorsement, the resolution recommended that manufacturers of OCs be encouraged to submit the required application and supporting evidence for FDA to consider approving an OTC switch for OCs.

Physicians and other health care providers are an important group of stakeholders in efforts to move OCs OTC, since they are the current gatekeepers to women's access to prescription contraception and FDA will likely consult them while considering an application for an OTC switch. Thus, already having support from major medical professional associations may help convince a manufacturer to submit a switch application for an OTC OC product. But having the support of individual clinicians will also be important in getting an application approved and in educating women about OCs OTC once they are available.

Several opinion pieces published in medical journals indicate that many physicians may have entrenched biases against this novel way of providing contraception. These pieces have shown concern that women might either ignore label warnings or not read them, or that they might not be able to self-diagnose contraindications; that women might be less adherent with consistent pill use if they do not receive counseling; and that they might avoid annual exams and screening for sexually transmitted infections (STIs) and cervical cancer.<sup>50</sup> There is little formal data documenting what physicians and other clinicians think about OTC OCs, though results from an electronic survey with Obstetrician/Gynecologist and Family Medicine residents found that the majority of respondents were against an OTC switch for both COCs and POPs, although respondents had more favorable views about OTC POPs. For those against moving a COC or POP over the counter, the majority stated the main reason for their opposition was safety concerns. Despite the low response rate (4%), the survey gives some idea of the negative perceptions that some physicians in training have about OTC OCs and identifies areas of misinformation among physicians regarding the safety of OCs used without a prescription.<sup>51</sup>

It is important to keep in mind that annual exams and STI and cancer screenings are not needed for contraception initiation.<sup>52</sup> However, evidence suggests that women continue to seek preventive care even when they obtain their pills OTC.<sup>53</sup> In addition, under the ACA, women are able to seek preventive care, including annual well-woman visits, without cost sharing,<sup>54</sup> this may make women even more willing to have their regular preventive health visits and screenings, whether they obtain their contraception over the counter or via a prescription.

#### **D. Would an OTC OC be relevant in the new health care environment?**

One of the cornerstones of the ACA is the guarantee that insurance cover a set of preventive health services with no cost sharing (i.e., no copayment, deductible, or coinsurance). This includes coverage of contraceptive methods and counseling, along with other women's preventive services and screenings.<sup>55</sup> HHS has provided further guidance about contraceptive coverage, specifically stating that insurers must cover the full range of FDA-approved contraceptives without cost sharing, including OTC methods (such as OTC EC, female condoms, and spermicide; male condoms are not included because the contraceptive coverage rule applies only to methods used by women). This means that a future OTC OC should be covered by insurance without a copay. However, HHS has specifically stated that insurers can require women to have a prescription to get coverage of OTC methods.<sup>56</sup>

The contraceptive coverage requirement should go a long way to making contraception more accessible and affordable for women. Most women will not have to pay a copay for the office visit where they get either a method such as an intrauterine device inserted or a prescription for a method like the pill, and they will not have a copay for the method itself. In 2011 and 2012, 27 million women gained expanded coverage with the preventive services benefit.<sup>57</sup> So an important question for advocates of moving OCs OTC is whether an OTC OC is still desirable and relevant, particularly since insurers can require a prescription for OTC methods, rendering the OTC benefit moot. But there are many reasons why pushing to move OCs OTC still makes sense, given this policy change.

First, not all insurance plans will have to comply with the contraceptive coverage requirement. Certain religious institutions are exempt from covering contraception for their employees,<sup>58</sup> as are grandfathered plans (those existing before March 23, 2010).<sup>59</sup> In addition, groups of women will remain uninsured even after the ACA takes full effect, in particular, some immigrant women who are not eligible to enroll in government-subsidized plans or to purchase insurance through state health exchanges.<sup>60</sup> Research conducted in Massachusetts after state health reform took effect showed that while the number of nonelderly insured adults increased from 86.6% to 94.2% between 2006 and 2010, certain groups of women “fell through the cracks” including immigrant women, minors, young women, women living outside urban areas, and those undergoing common life transitions like pregnancy, marriage, moving, or graduating from school.<sup>61</sup> An OTC OC would therefore provide a highly effective pregnancy-prevention option for women who are uninsured or underinsured with regard to contraception. An OTC OC could also provide an important stopgap for insured women who run out of their prescription pills or forget to bring them on vacation or a business trip.

However, policy solutions are needed to ensure that women can use their insurance for an OTC OC without a prescription. When EC went over the counter, its steep retail price of \$32 to \$65 for branded products and \$26-\$62 for generics<sup>62</sup> made it unaffordable for many women. While the manufacturer of a future OTC OC needs to price its product affordably so that women of diverse income levels can access it, insurance coverage is also critically important. But having to get a prescription in order to get insurance coverage reverses the benefits of OTC access.

To address this, HHS should strike “as prescribed” from the contraceptive coverage requirement and require or encourage insurance plans to cover OTC contraceptives without a prescription. Though the rule does not prohibit insurers from using alternatives to the prescription, the prescription is the standard protocol for tracking billing and preventing fraud, and most insurers will continue to use it without being prompted to change their practices. But alternatives to the prescription model do exist that could serve as a model for insurers. In some state Medicaid programs, OTC EC is covered without a prescription.<sup>63</sup> In these states, pharmacists are instructed to use their own pharmacist identifier or a dummy billing code in place of the clinician identifier provided by CMS. This allows a woman enrolled in Medicaid to walk into a pharmacy, show her Medicaid card to the pharmacist, and walk out with OTC EC.<sup>64</sup>

Medicaid as a whole warrants discussion in regards to insurance coverage of a future OTC OC. Medicaid is the joint federal-state program for eligible low-income individuals and, like other

public insurance programs, is not subject to the contraceptive coverage rule (although Medicaid Alternative Benefit Plans, the Medicaid “expansion” plans created by the ACA, are subject to the preventive services rules).<sup>65</sup> However, Medicaid mandates coverage of family planning services and supplies, although it allows states to determine exactly which methods and formulations are covered. Coverage of OTC drugs and medications is optional, with most states electing at least some OTC coverage, and a prescription is required to receive reimbursement with federal funds.<sup>66</sup> While in 2007 49 states covered OTC medications like covered allergy, asthma, and sinus medications, and 35 covered smoking-cessation products,<sup>67</sup> according to a 2007-2008 survey of Medicaid programs, only about half of states covered OTC EC.<sup>68</sup> Considering that Medicaid serves low-income women who are at higher risk of unintended pregnancy and face the greatest barriers to accessing contraception, solutions are needed to ensure that women enrolled in Medicaid are able to use their insurance to access OTC contraception without a prescription. Changing federal Medicaid policy so that a prescription is not required for federal reimbursement for OTC contraceptives might give more states the incentive to include coverage of OTC contraceptives in their programs.

It is also important that other public insurance programs like the Indian Health Service (IHS), TRICARE, and Veterans Affairs that are not subject to the contraceptive coverage requirement cover OTC contraceptives without a prescription. The Department of Defense, which oversees TRICARE and IHS recently issued directives to cover OTC EC with no cost sharing,<sup>69</sup> but this should be expanded to all OTC contraceptives so that a future OTC OC is covered as well.

## V. IMPACT OF POLICY RECOMMENDATIONS

Despite the many prescription and OTC contraceptive products on the market today, women continue to face barriers to accessing safe, highly effective contraception, and half of pregnancies in the United States are unintended.<sup>70</sup> Running out of pills and not having a pill pack on hand are common reasons women miss taking pills, and gaps in use put women at high risk of unintended pregnancy. A majority of women support moving OCs OTC and many women not currently using a method, or using a less effective method, say they would use OCs if one were available over the counter.<sup>71</sup> Research also shows that OTC access may improve pill continuation. An OTC OC could help more women prevent pregnancy, would give women more control over their reproductive lives, and could reduce unintended pregnancy. This could result in savings to the health system.

In the event of an OTC switch for a POP, most women using OCs would likely continue using their current method and would continue to see their providers in order to obtain their OC of choice. But even if more formulations of OCs were to go over the counter, women would still be able to seek guidance from their providers about which formulation is best for them. And research indicates that women seek preventive care and screenings even if they are able to get their birth control OTC or directly from a pharmacy.<sup>72</sup>

Though the ACA will vastly improve contraceptive access by requiring most insurers to cover contraception without cost sharing, some groups of women will not benefit, including those who are insured by religious institutions and those who remain uninsured, including some immigrant women. For these groups of women, along with women who are between insurance plans and

who forget to bring their prescription pills on vacation or a work trip, an OTC OC could enable continuous contraceptive access.

But issues involving insurance coverage for currently available OTC contraceptives and a future OTC OC need to be addressed in order for all women to reap the benefits of the availability of an OTC OC. All public and private insurance plans should cover OTC contraceptives without cost sharing and without requiring a prescription. To identify alternatives to the prescription, insurers should look for models such as state Medicaid programs that cover OTC EC without a prescription, as well as IHS and TRICARE, which recently changed their policies so that women insured by these plans can obtain OTC EC without a prescription or extra costs. Helping women more easily access their method of choice and prevent unintended pregnancy could result in cost savings for insurers and the health system as a whole.

## VI. CONCLUSION

The invention of the birth control pill revolutionized society, empowering women and couples to decide whether and when to have children and allowing women to make significant gains in the social, economic, and political sectors. But unintended pregnancy rates in the United States still hover close to 50%, with barriers to contraceptive access and gaps in use contributing to that rate. Moving OCs OTC could help to address this problem, at the same time giving women more control over their reproductive health and lives.

The ACA is a major achievement for health policy and promises to give millions of Americans access to health insurance that includes coverage of preventive health services that are critical to the health of individuals, families, and communities. That contraception is included in the list of services covered with no cost sharing is significant; never before has there been as far reaching a policy intended to expand contraceptive coverage. Another important policy milestone is that after years of court battles, brand name and generic levonorgestrel EC is finally available over the counter for women of all ages.<sup>73</sup> In this context of groundbreaking health reform and expanded accessibility of contraception in the United States, it is time to move OCs OTC.

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