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Moving Oral Contraceptives to Over-the-Counter Status: Policy Versus Politics

By Sneha Barot

Reproductive health programs and key providers of reproductive health care are under siege in the United States. Social conservatives in Congress are attempting to wipe out funding for the Title X national family planning program, negate the guarantee of contraceptive coverage under the Affordable Care Act (ACA) and defund Planned Parenthood at the national and state levels. While they wage an aggressive campaign against meaningful access to contraception, a few among their ranks have latched onto an idea to soften their anti–birth control image by advocating for over-the-counter (OTC) status for oral contraceptive pills. Some used this issue to great effect during the 2014 elections.

Despite the politicization of the issue, there is a strong evidence-based case in favor of moving oral contraceptives OTC. Reproductive health advocates and medical experts have been discussing the merits of removing the prescription requirement for the pill for many years. But the process for making that happen involves the drug manufacturers and the Food and Drug Administration (FDA), not Congress. Achieving OTC status certainly would reduce barriers to this popular method of birth control for some women. Although it would be insufficient as a stand-alone strategy to ensure contraceptive access, it would be an important component of a multifaceted strategy to preserve and enhance access to the wide range of contraceptive methods that people need throughout their reproductive lives.

HIGHLIGHTS

- *There is a strong, evidence-based case for moving oral contraceptives to over-the-counter (OTC) status, without age or cost barriers.*
- *Some social conservatives, especially those from swing states, have latched onto the issue of OTC oral contraceptives to counter their anti-contraception image, even as they continue their efforts to dismantle the very programs and policies that support increased access to contraceptives.*
- *OTC oral contraceptives would represent an important advancement and complement to other strategies to enhance women's access to the full range of contraceptive methods, but is insufficient as a stand-alone strategy and would be a poor replacement for insurance coverage of contraceptives.*

The Process and Rationale for OTC

Most people want to plan whether and when to have children, because they understand that an unintended pregnancy can have significant social, economic and health consequences for themselves and their families.[1,2] Yet, about half of all U.S. pregnancies are unintended.[3] Minority women and those who are low-income, aged 18–24 or cohabiting face the highest rates of unintended pregnancy and could benefit particularly from increased access to contraceptives.[4]

Lifting the prescription requirement for oral contraceptives could lower barriers to access this highly popular method of pregnancy prevention. Indeed, U.S. women rely on the pill more than any other method. In 2012, 26% of contraceptive users relied on the pill; the next most commonly used methods were female sterilization (25%) and male condoms (15%).[5] Increasing access to the pill by making it available OTC could improve contraceptive use and, in turn, lower unintended pregnancy rates, especially among women who

are uninsured and those who lack the time, would need to arrange for child care or otherwise would find it difficult to visit a health care provider to obtain a prescription.

The typical and onerous process for switching any drug to OTC status requires a drug manufacturer to submit an application to the FDA for a specific formulation. The FDA—on the basis of criteria regarding the ability of consumers to safely, effectively and correctly use the medication without professional guidance—decides whether to grant the request. The evidence is quite strong that oral contraceptive pills meet the FDA criteria.[6] Specifically, women are able to determine if they are at risk of unintended pregnancy and whether use of the drug is appropriate. Women can take the medication effectively without instructions from a medical professional. Oral contraceptives are neither addictive, nor toxic in the case of misuse. And finally, women are able to take the pill safely without a doctor's screening, as they can self-screen for contraindications. For all these reasons, and because it would help more women take more control over their own fertility, leading medical groups—including the American Medical Association,[7] American College of Obstetricians and Gynecologists[8,9] and American Academy of Family Physicians[10]—have endorsed making the pill OTC.

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Although all forms of the pill are extremely safe for most women, combined oral contraceptives—which contain estrogen—may increase the risk of vascular complications (e.g., blood clots, heart attacks, strokes) among women with certain contraindications (e.g., hypertension, smokers aged 35 or older).[11] However, research shows that women are able to use a checklist to self-screen for contraindications and appropriately determine if oral contraceptives are safe for them.[12,13]

Compared with combined oral contraceptives, progestin-only pills—often called "mini-pills"—do not pose the same risk for vascular complications, and have fewer and rarer contraindications. Therefore, the mini-pill would most likely be the first type of oral contraceptive approved for OTC status.[14] (Indeed, there is precedent from another progestin-only contraceptive, levonorgestrel emergency contraception, which is the only hormonal contraceptive product available OTC in the United States.) However, only 4% of pill users rely on the mini-pill, as the method is generally favored by women who are postpartum or have contraindications to combined oral contraceptives.[15] This may be because the method's more demanding regimen (requiring the pill to be taken at the same time every day of the month or potentially face lowered efficacy) and its most common side effects of breakthrough bleeding and missed periods discourage women from using it.

For any formulation of a birth control pill to switch to OTC status, a pharmaceutical company would need to initiate an often lengthy and expensive process that entails research (including studies of label comprehension and consumer actual use) and review by the FDA. This alone can be a deterrent from a business perspective. Some companies may also be wary of getting embroiled in a potentially controversial issue, given the intense, years-long political firestorm that ensnared the FDA process to switch emergency contraception to OTC status (see "Obama Administration Yields to the Courts and the Evidence, Allows Emergency Contraception to Be Sold Without Restrictions," Spring 2013).

No Silver Bullet

Reproductive health researchers and advocates working on OTC contraceptives have been wrestling over the years with a number of concerns about a status switch for the pill. Some health care advocates and providers believe that it is

important to retain screenings for users' eligibility for contraception because those visits allow health care providers to counsel patients on other contraceptive methods (such as long-acting reversible contraceptives) and provide other reproductive health counseling and services, such as STI prevention services and pelvic exams—even though such services are not medically required for using the pill.

Many experts fear that in response to conservative demands, the FDA or other policymakers might impose an age restriction on an OTC product, which would limit access for adolescent and young women. These age-groups face a greater risk of unintended pregnancy and more barriers to accessing contraceptives than older women—and therefore have the most to gain from an OTC status switch. Additionally, an age requirement would, by definition, mean an identification requirement, which would be a disadvantage not only for adolescent and young women without government-issued photo IDs, but for immigrants as well, particularly those who are undocumented.

One of the areas of greatest concern involves cost and insurance coverage. If the pill's status is successfully switched, but the price of an OTC product is high (as has been the case with emergency contraception), then one access barrier simply will replace another. Thus, it would be even more important that public and private insurance coverage of an OTC product is ensured. Under the ACA, most private health insurance plans must cover the full range of women's contraceptive methods and services, without out-of-pocket costs to the patient. Under this policy, insurers must cover OTC contraceptives, but only if women obtain a prescription—which essentially negates the benefits of OTC status, especially for women who are concerned about costs.

Under public insurance programs such as Medicaid, states vary in their coverage of OTC contraceptives. Many states have chosen to cover OTC emergency contraception if the woman obtains a prescription. However, some state Medicaid programs have gone further and cover emergency contraception without a prescription; this level of coverage has also been adopted by the Indian Health Service and the U.S. military's TRICARE insurance program.

If and when oral contraceptives go OTC, insurance coverage will be one of the most critical factors in determining whether they will be both accessible and affordable to women. In the meantime, several states are pushing forward with efforts to remove barriers and increase access to hormonal contraceptives (see box). Such measures, while limited in scope, are both promising and useful as models that could be replicated nationwide.

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Divergent Agendas

Even though reproductive health advocates and researchers have been working on the issue of OTC status for oral contraceptives for over a decade, the issue caught fire in the 2014 campaign cycle. On the surface, it appeared that both sides of the birth control debate had found common ground. Conservatives, including those who had taken a hard-line stance against reproductive rights, saw OTC birth control as a winning strategy to deflect allegations that they were waging a "war on women." One high-profile example played out midway through a very tight Senate race in Colorado, where socially conservative Republican Cory Gardner unexpectedly declared his support for OTC birth control after repeatedly coming under attack for his record of opposing policies to support access to contraception. It became a turning point in Gardner's campaign, and other Republican candidates quickly followed suit, especially those in swing races. The strategy

Innovative Approaches at the State Level

In the absence of OTC status for almost all hormonal contraceptives, states have been exploring other intermediate measures. Two recently enacted strategies specific to birth control at the state level include pharmacy provision of birth control prescriptions and a requirement for insurance plans to cover a 12-month supply of pills at one time.

Under the pharmacy access model, the state gives pharmacists the authority to prescribe hormonal contraceptives. Two states, California and Oregon, have passed such laws and are developing regulations to put them into effect. In both states, pharmacists will provide a self-screening questionnaire to women to check for contraindications. The California law allows pharmacists to prescribe a range of hormonal contraceptive methods, which includes oral contraceptives, the patch, the vaginal ring and the injectable, according to draft regulations.[16] Oregon's law specifically allows pharmacists to prescribe oral contraceptives and contraceptive patches to women who are 18 or older; those younger than 18 are eligible only if they have obtained at least one previous prescription from a clinician. Also, the state of Washington has explored pharmacy provision of oral contraceptives through pilot studies. Although these states have not adopted true OTC models, they have moved closer to this goal through their "behind-the-counter" approach. Still, there are anticipated challenges to implementing these state laws: For example, it is unclear how pharmacists will be able to bill insurance companies for the costs of associated counseling and screening services.

In addition, Oregon and the District of Columbia enacted bills this year to require insurance plans to cover a yearlong supply of oral contraceptive pills. In general, insurance companies have only allowed coverage for a one- or three-month supply of birth control pills. Yet, researchers have found that increasing the number of pill packs supplied to women may lead to more consistent contraceptive use and a lower likelihood of unintended pregnancy.[17,18] This idea has bubbled up to the federal level, where family planning advocates in Congress see it as another potential strategy to try nationwide. In July, Reps. Jackie Speier (D-CA) and Suzanne Bonamici (D-OR) sent a letter signed by 53 other members of the House of Representatives to the secretary of the Department of Health and Human Services (DHHS). In the letter, they asked DHHS to use its existing authority to issue guidance requiring insurance plans to cover a 12-month supply of birth control, without cost-sharing.[19]

proved successful for Gardner and several others who used it.

Taking what started as a campaign strategy one step further, Sens. Gardner and Kelly Ayotte (R-NH)—along with several other Republican cosponsors—introduced the Allowing Greater Access to Safe and Effective Contraception Act in 2015. The bill would create special incentives for manufacturers of birth control pills to file an OTC-switch application with the FDA. Specifically, it would grant these applications priority review by the FDA and waive the filing fee. The bill stipulates, however, that OTC access would be allowed only for those aged 18 or older.

In an interview, Susan Wood—who is widely known for resigning her position as the FDA's assistant commissioner for women's health in 2005 when the FDA delayed OTC approval for emergency contraception—commented that the bill would inappropriately politicize a process that should be guided by science and public health.[20] Wood pointed out that the "FDA's review and approval process should be driven by the evidence, and not by interventions by Congress or the administration." She noted that the age restriction barring minors from future OTC availability, for example, clearly is driven by politics, because it is not medically justified in terms of safety or efficacy. In fact, preventing OTC access for adolescent women would be counterproductive and harmful to helping them avoid unplanned pregnancies and the negative health, social and economic consequences that often follow. In addition, Wood noted that according special status to an

OTC application for oral contraceptives is not warranted: "We have to ensure that women's health products are treated as routinely as other drugs. Special privileges such as fast track status and fee waivers set up a structure founded on an assertion that reproductive health products are different and require interventions—such as age requirements—when they're not necessary. They don't need beneficial treatment any more than they need to have special limitations."

One of the most problematic aspects of the bill is that it does not address the issue of insurance coverage of an OTC pill. This is no surprise, as its sponsors have repeatedly pushed to repeal the ACA's contraceptive coverage guarantee and the ACA more generally. Rhetoric notwithstanding, OTC status for certain birth control pills would be no substitute for the ACA policy. That policy encompasses the full array of contraceptive methods, not just the pill. This matters for women's ability to choose the method that is best for them, which is especially important given that more than half of women use four or more contraceptive methods over the course of their life because of their changing needs.[21] Additionally, the ACA policy requires plans to cover methods without any out-of-pocket costs. Such costs can be a significant barrier to using methods like the pill or the ring, and can be particularly problematic for methods like the IUD or implant, which are highly effective and cost-effective but have high up-front costs. And, because methods like the IUD and implant require a trained provider for insertion, they cannot be made available OTC. Among oral contraceptives, there are dozens of brands and formulations of pills that are not medically interchangeable; as such, making one or even several versions OTC would not help all pill users.

The bill is also flawed because it rests on the false assumption that switching a drug from prescription-only to OTC status will inevitably lower its costs.[22,23] Conveniently, the bill's supporters have ignored the only example of an OTC hormonal contraceptive, emergency contraception, the cost of which has remained high and barriers to access have thus persisted since the prescription requirement was removed. To partially address the issue of cost, the bill looks to Health Savings Accounts and Flexible Spending Accounts—which allow people to put aside a tax-free pot of savings for health care expenses—to pay for OTC drugs without a prescription. Although this option might benefit some better-off women, it would be useless for lower income women who cannot afford to set aside those pre-tax earnings up front and who would save little from the tax deduction. In sum, the approach of these social conservatives—that is, their OTC birth control bill combined with repealing the ACA and its contraceptive coverage guarantee—would lead to new cost barriers to all methods of birth control for many women in exchange for easier access to a single form of the pill for women who can afford it.

OTC status for oral contraceptives is one strategy to improving access, but it would not and could not fulfill the wide range of needs of all people, especially if cost and age barriers were attached to any product.

Sen. Patty Murray (D-WA), a champion of reproductive health and rights, introduced her own version of a bill on this topic along with 30 Democratic cosponsors just three weeks after Ayotte and Gardner introduced their bill. The Affordability Is Access Act, also pending in the House, was designed to expose the key fallacies in the OTC approach endorsed by some social conservatives. In contrast to that approach, Murray's bill would require private insurance companies to cover any OTC pill even without a prescription. The bill states that oral contraceptives "must be both easier to obtain and affordable" and that "to make it either easier to obtain or more affordable, but not both, is to leave unacceptable barriers in place for women." Moreover, the bill does not include any age restrictions, would not interfere with the FDA process and would protect customers against

interference by retailers with objections to OTC contraceptives. The Murray bill certainly moves in the right direction and is premised on complementing—not replacing—existing advances in reproductive health and rights policy. It too, however, represents more of a political talking point than a coherent approach to good policy. For example, the bill is designed to apply to private insurance but not Medicaid or other forms of coverage, and it stops short of extending insurance coverage to OTC contraceptive methods besides the pill, such as emergency contraception and condoms.

Comprehensive Solutions

Social conservatives have only escalated their battle against birth control in recent months, and it is likely this campaign will continue as the national elections approach. Even the small nod from a handful of conservative lawmakers in favor of placing a single method of birth control OTC for adult women is controversial among those conservatives who insist on conflating birth control with abortion (see "Contraception Is Not Abortion: The Strategic Campaign of Antiabortion Groups to Persuade the Public Otherwise," Fall 2014). Despite their disagreements over this tactic, conservatives' record of hostility is clear when it comes to government programs and policies that depend on lawmakers to appropriate funds and support the providers who deliver sexual and reproductive health services to women and men.

If policymakers truly wish to expand contraceptive access, they need to take a comprehensive approach that works for people of all ages and incomes, and covers the full range of contraceptive methods, services and care. Certainly, OTC status for oral contraceptives is one strategy to improving access, but it would not and could not fulfill the wide range of needs of all people, especially if cost and age barriers were attached to any product. The contraceptive coverage guarantee under the ACA goes a long way toward meeting those needs, but it also has limitations, which could be addressed by covering more women and dropping the need to obtain a prescription for OTC coverage. Policymakers could demonstrate their seriousness in advancing reproductive health by strengthening contraceptive coverage under the ACA, rather than seeking to undermine it. They also could commit to supporting rather than attacking safety-net family planning centers, increasing funding for the Title X domestic family planning program, advocating for additional states to adopt the ACA's Medicaid expansion, promoting comprehensive sexuality education, and encouraging and increasing funding for research and development of new contraceptive technologies. This is what meaningful support for contraceptive access looks like. ■

REFERENCES

1. Guttmacher Institute, Testimony of Guttmacher Institute, submitted to the Committee on Preventive Services for Women, Institute of Medicine, 2011, http://www.guttmacher.org/pubs/CPSW-testimony.pdf.

2. Sonfield A et al., *The Social and Economic Benefits of Women's Ability to Determine Whether and When to Have Children,* New York: Guttmacher Institute, 2013, http://www.guttmacher.org/pubs/social-economic-benefits.pdf.

3. Guttmacher Institute, Unintended pregnancy in the United States, *Fact Sheet,* New York: Guttmacher Institute, 2015, http://www.guttmacher.org/pubs/FB-Unintended-Pregnancy-US.html.

4. Finer LB and Zolna MR, Shifts in intended and unintended pregnancies in the United States, 2001–2008, *American Journal of Public Health,* 2014, 104(S1):S44–S48, http://www.guttmacher.org/pubs/journals/ajph.2013.301416.pdf.

5. Guttmacher Institute, Contraceptive use in the United States, *Fact Sheet,* New York: Guttmacher Institute, 2015, http://www.guttmacher.org/pubs/fb_contr_use.html.

6. Wahlin B, Grindlay K and Grossman D, Should oral contraceptives be available over the counter? *Food and Drug Policy Forum,* 2014, 4(3):1–18.

7. American Medical Association, D-75.995 Over-the-counter access to oral contraceptives, no date, http://www.ama-assn.org/ssl3/ecomm/PolicyFinderForm.pl?site=www.ama-assn.org&uri=%2fresources%2fhtml%2fPolicyFinder%2fpolicyfiles%2fDIR%2fD-75.995.HTM.

8. American College of Obstetricians and Gynecologists, Committee opinion no. 615: access to contraception, *Obstetrics & Gynecology,* 2015, 125(1):250–255, http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Access-to-Contraception.

9. American College of Obstetricians and Gynecologists, Committee opinion no. 544: over-the-counter access to oral contraceptives, *Obstetrics & Gynecology,* 2012, 120(6):1527–1531, http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Over-the-Counter-Access-to-Oral-Contraceptives.

10. American Academy of Family Physicians, Over-the-counter oral contraceptives, no date, http://www.aafp.org/about/policies/all/otc-oral-contraceptives.html.

11. Curtis KM et al., U.S. medical eligibility criteria for contraceptive use, 2010: adapted from the World Health Organization medical eligibility criteria for contraceptive use, 4th edition, *MMWR,* 2010, 59(RR04):1–6, http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5904a1.htm.

12. Shotorbani S et al., Agreement between women's and providers' assessment of hormonal contraceptive risk factors, *Contraception,* 2006, 73(5):501–506.

13. Grossman D et al., Accuracy of self-screening for contraindications to combined oral contraceptive use, *Obstetrics & Gynecology,* 2008, 112(3):572–578.

14. OCs OTC Working Group, Moving oral contraceptives over-the-counter: frequently asked questions about what we know and what we still need to know, 2014, http://ocsotc.org/?page_id=7#POPs.

REFERENCES continued

15. Liang S, Grossman D and Phillips KA, User characteristics and out-of-pocket expenditures for progestin-only versus combined oral contraceptives, *Contraception,* 2012, 86(6):666–672.

16. California Board of Pharmacy, Proposed regulation: §1746.1 protocol for pharmacists furnishing self-administered hormonal contraception, no date, http://www.pharmacy.ca.gov/laws_regs/1746_1_pt.pdf.

17. Steenland MW et al., How does the number of oral contraceptive pill packs dispensed or prescribed affect continuation and other measures of consistent and correct use? A systematic review, *Contraception,* 2013, 87(5):605–610.

18. Foster DG et al., Number of oral contraceptive pill packages dispensed and subsequent unintended pregnancies, *Obstetrics & Gynecology,* 2011, 117(3):566–572.

19. Speier J et al., Letter to the Honorable Sylvia Burwell, Jul. 2, 2015, http://bonamici.house.gov/sites/bonamici.house.gov/files/7-2-15%20Congressional%20Letter%20to%20HHS%20re%2012%20mo%20bc%20dispensing.pdf.

20. Wood S, George Washington University, Washington, DC, personal communication, Aug. 12, 2015.

21. Daniels K, Mosher WD and Jones J, Contraceptive methods women have ever used: United States, 1982–2010, *National Health Statistics Reports,* 2013, No. 62, http://www.cdc.gov/nchs/data/nhsr/nhsr062.pdf.

22. Office of Sen. Cory Gardner, Ayotte, Gardner introduce bill aimed at increasing availability of safe and effective over-the-counter contraceptives, news release, May 21, 2015, http://www.gardner.senate.gov/newsroom/press-releases/ayotte-gardner-introduce-bill-aimed-at-increasing-availability-of-safe-and-effective-over-the-counter-contraceptives.

23. Ayotte K, My turn: contraception bill is a win for women's health, *Concord Monitor,* May 27, 2015, http://politics.concordmonitor.com/2015/05/congressional-delegation/my-turn-contraception-bill-is-a-win-for-womens-health.

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