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Dear OCs OTC Working Group Member,

Thank you for all of the support you have shown us after the announcement of our partnership with HRA Pharma to make an OTC OC in the US a reality. We are thrilled by all of the positive responses from members of the working group, the media, and general public. Below, you will find some of the many media articles that picked up the news from the original piece in <u>Vox</u>.

Also in this newsletter, we provide an update on the Women's Preventive Services Initiative, the reintroduction of a bill on OCs OTC in the US Congress, a report on some misinformation on birth control in the national media, an update from a citizen petition for OCs OTC, and policy overviews on contraceptive coverage.

The new year will likely present many challenges related to birth control access, some of which we detail in this newsletter. We remain committed to protecting and advocating for insurance coverage of all birth control methods and to working with you all to ensure we maintain and expand on the progress we have made.

Thanks,

Kate Grindlay Project Director/Associate Ibis Reproductive Health

News articles featuring partnership with HRA Pharma

Brit & Co: Over the counter birth control could be happening VERY soon Hello Giggles: Over the counter birth control might be coming out way sooner than we thought HerCampus: Over-the-counter birth control pills may be headed our way...In a few years NY Mag The Cut: We're only a few years away from over-the-counter birth control pills OTC.NewDirections: Ibis and HRA aim to switch the pill to OTC Our Bodies Ourselves: Over-the-counter birth control pill on its way to the U.S.A. The Outline: Will women in the US ever get over-the-counter birth control pills? And why don't we have them already? Oxygen: Over-the-counter birth control may be a real thing soon Pharmacy Times: An OTC birth control pill could become a reality PopSugar: Over-the-counter birth control might be available soon - but why isn't it already? Shape Magazine: You might be able to buy birth control pills over the counter soon Sheknows.com: We're one step closer to getting birth control pills without a prescription Teen Vogue: Over-the-counter birth control may finally be happening TIME Motto: Over-the-counter birth control might soon become a reality

Women's Preventive Services Initiative update

In December, the Health Resources and Services Administration (HRSA) issued <u>the updated</u> <u>preventive services</u> for women that most private insurance plans are required to cover without cost sharing, accepting the clinical recommendations made by the <u>Women's Preventive</u> <u>Services Initiative</u> (WPSI). The WPSI is a coalition of national health professional organizations and consumer and patient advocates convened to review the evidence and develop, review, and update recommendations for the Women's Preventive Services Guidelines. The updated guidelines reaffirm insurance coverage of the full range of female-initiated contraceptives without cost sharing. This includes the 18 female-initiated methods approved by the FDA and methods that may be approved in the future. You can find the abridged report <u>here</u>.

OCs OTC bill reintroduced in Congress

Senators Ernst (R-IA) and Gardner (R-CO) and Representatives Comstock (R-VA) and Love (R-UT) reintroduced the *Allowing Greater Access to Safe and Effective Contraception Act* in the <u>Senate</u> and the <u>House</u>. This bill, originally introduced in 2015, would expedite the process for FDA review of an application for an OTC OC and provide incentives for manufacturers who pursuing an OTC switch for an OC product. Unfortunately, this bill does not address the need for insurance coverage for contraceptives and would provide incentives to manufacturers only if their products are available for women aged 18 and over. It also raises concern about congressional influence on the FDA process. We have yet to learn of any reintroduction of the *Affordability is Access Act*, also introduced in the <u>House</u> and <u>Senate</u> in 2015. This bill would guarantee insurance coverage of a future OTC OC.

Misinformation about birth control from health-related Trump appointments

Working group member Krishna Upadhya, based at Johns Hopkins School of Medicine and and a working group member, was featured in an article from the <u>Huffington Post</u> disproving false comments from <u>Katy Talento</u>, who will service on President-elect Trump's Domestic Policy Council, implying that hormonal contraceptives cause miscarriage, abortion, and infertility, among other consequences.

The nomination of Tom Price for Secretary of Health and Human Services <u>drew attention</u> to comments he made in 2012 doubting that there were any women in the US who could not afford birth control. Working group member Renee Bracey Sherman, based at the <u>National Network of Abortion Funds</u>, wrote a response to this comment in <u>Refinery 29</u> that supports what we commonly hear from women about barriers to obtaining birth control, such as cost. The National Campaign to Prevent Teen and Unplanned Pregnancy is conducting <u>a</u> <u>campaign</u> to help more people share their stories about birth control to highlight barriers women face in accessing contraception and the importance of protecting the Affordable Care Act's contraceptive coverage guarantee.

Response from the FDA on citizen petition for OCs OTC

The US Food and Drug Administration (FDA) issued a response in December to a citizen petition from Larry Pilot, an attorney and the former director of the FDA's Bureau of Medical Devices, to "authorize acquisition of oral contraceptive drug products through over-the-counter purchase." Currently, all letters are publicly available for download <u>here</u>. See <u>here</u> for a copy of the FDA denial letter. This rejection letter provides a perspective from the agency on moving OCs OTC. It outlines the research that needs to be done and the pathway for getting an OC through the OTC-approval process.

Guttmacher and Kaiser contraceptive policy overviews

The Guttmacher Institute recently released a report detailing "<u>What is at stake with the federal contraceptive coverage guarantee</u>?" and the Kaiser Family Foundation also published "<u>The future of contraceptive coverage</u>." These reports provide detailed information on the ways the contraceptive coverage guarantee of the Affordable Care Act (ACA) has removed many of the cost barriers to obtaining birth control. The ACA is under attack with the new administration and Congress. Removing the contraceptive coverage guarantee of the women and families who benefit from it. Insurance coverage is a priority for the working group and we are keeping an eye on all proposals concerning the ACA.

About us

The Oral Contraceptives (OCs) Over-the-Counter (OTC) Working Group is a coalition of reproductive health, rights, and justice organizations, nonprofit research and advocacy groups, university-based researchers, and prominent clinicians who share a commitment to providing all women of reproductive age easier access to safe, effective, acceptable, and affordable contraceptives. The working group was established in 2004 to explore the potential of over-the-counter access to oral contraceptives to reduce disparities in reproductive health care

access and outcomes, and to increase opportunities for women to access a safe, effective method of contraception, free of unnecessary control, as part of a healthy sexual and reproductive life.

The working group is coordinated by Ibis Reproductive Health.



www.ibisreproductivehealth.org

Contact us

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