

December 15, 2017

In This Update

[Hormonal contraceptives and breast cancer](#)

[HHS Secretary nominee on OCs OTC](#)

[Massachusetts contraceptive coverage law](#)

[New Zealand pharmacist-prescribing update](#)

[Closing the gender gap in tech through protecting women's health](#)

[SOP sign-ons](#)

[About us](#)

[Contact us](#)

Dear Working Group member,

A new [study](#) from Denmark links hormonal contraceptive use to an increase in breast cancer. Below we outline some of the key points of the study and interrogate its findings. See also this [letter to the editor](#) in the *New York Times* written by working group members Diana Greene Foster, Daniel Grossman, and Eleanor Bimla Schwarz. Also in this newsletter, we share a recent article on the US Department of Health and Human Services Secretary nominee's stance on OTC OCs, an update on new pharmacist prescribing of OCs in New Zealand, and an op-ed by working group member Monica Harrington on how tech companies can close the gender gap by improving women's reproductive health coverage, including for a future OTC OC. Finally, we highlight our latest sign-ons to the statement of purpose.

We would also like to congratulate advocates from Massachusetts whose contraceptive coverage bill was signed into [law](#) last month. It will require coverage for contraceptive drugs, devices, and products without co-pay and emergency contraception without a prescription. It will also require insurance plans to cover up to a 12-month supply at once after an initial three-month supply.

Please feel free to reach out to us with any questions.

Thank you,

A handwritten signature in black ink that reads "Kate". The signature is written in a cursive, lowercase style.

Kate Grindlay Kelly
Project Director/Associate
Ibis Reproductive Health

Study on the link between hormonal contraceptives and breast cancer

A [recent study](#) conducted by Morch and colleagues at the University of Copenhagen examined the link between hormonal birth control and breast cancer. While the study cites an elevated risk of breast cancer of 20% (95% CI: 14%-26%) among current or recent users of hormonal contraception compared to never users, the effect is small in absolute numbers, equating to 13 additional cases of breast cancer per 100,000 current and recent users of hormonal contraception aged 15-49 (95% CI: 10-16) in one year. It may be the case that current or recent users of oral contraceptives interact with the medical system at higher rates than those who never used hormonal contraception and are therefore potentially more likely to get regular breast exams or mammograms. Furthermore, the authors do not account for other advantages of hormonal methods to present a full picture of the risks and benefits, including potential prevention of other types of cancer, reduction in mortality overall, or non-contraceptive benefits women gain from these methods including the life and well-being benefits of being able to plan when to have children and to complete education or pursue a career.

The study takes advantage of the Danish national health registry to follow women aged 15-49 from 1995 to 2012. The period of time covered by the study allowed the researchers to examine more recent formulations of birth control pills that use lower doses of estrogen than those that were first on the market and that were the subject of most previous research linking hormonal contraceptives to breast cancer.

The study found a small, significant increase in the risk of breast cancer among current users of hormonal contraception. The study cites an elevated risk of 20% (95% CI: 14%-26%) among current or recent users of hormonal contraception compared to never users, which out of context may seem like a large increase. However, when put in terms of absolute risk, a 20% increase in risk equates to 13 additional cases of breast cancer per 100,000 current and recent users of hormonal contraception aged 15-49 (95% CI: 10-16) in one year. The majority of these cases were observed in women over age 40. Among women younger than age 35, there were an estimated two extra breast cancer cases per 100,000 current or recent users of hormonal contraception (95% CI: 1-4) compared to never users in one year.

Given the size of the dataset used for this study, the authors were able to examine the differences between different formulations of hormonal birth control and generally found that all formulations, including hormonal intrauterine devices, increased the risk of breast cancer compared to never users. The authors also found that risk of breast cancer increased with longer duration of use and remained elevated at least up to five years after discontinuation.

However, the results from this study should not be interpreted as casual evidence that hormonal contraception causes breast cancer. This study is observational in nature, and although authors did adjust for some confounding factors in their analyses including education level, family history of breast cancer, and parity, they did not control for other known risk factors for breast cancer including age at first [menstruation](#), history of [breastfeeding](#), alcohol consumption (see [here](#) and [here](#)), or physical [inactivity](#). The authors did control for tobacco use, body mass index, and age at first birth among parous women in a sensitivity analysis, but this analysis could suffer from selection bias as the rates of missingness for these variables was high and these variables were only available for parous women. A difference in screening may also potentially explain some of the increased risk picked up in this study. It may be the case

that women who are current or recent users of oral contraceptives are interacting with the medical system at higher rates than those who never used hormonal contraception and are therefore potentially more likely to get regular breast exams or mammograms.

Although this study adds a piece of evidence to a body of literature associating hormonal contraception with breast cancer, the findings are not new or surprising. The results of this study align with findings from previous studies examining the link between hormonal [contraception](#) and breast cancer. Despite the small increase in risk among users, users of hormonal contraception should weigh the benefits of hormonal contraception with the risks. Beyond the obvious contraceptive benefits that allow users to plan their reproductive lives, oral contraceptives are associated with substantial reductions in the risks of ovarian (see [here](#) and [here](#)), [endometrial](#), and [colorectal](#) cancers later in life and multiple studies have linked use of oral contraception to a decrease in overall [mortality](#) or have observed no effect (see [here](#), [here](#), and [here](#)) on overall mortality. They are also used for treatment of other medical disorders such as endometriosis-associated pain or irregular or excessive [bleeding](#). Physician and expert responses (see [here](#), [here](#) and [here](#)) to this article highlight that women, especially younger women, should not change their choice in contraception because of this study and should consider the benefits of each method of contraception alongside the potential risks. For other responses to this article, see the [NPR](#) and [Boston.com](#) articles.

HHS Secretary nominee elusive on support for OTC OCs

Alex Azar, nominee for Secretary of the US Department of Health and Human Services, was recently questioned about his stance on the prospect of a future OTC OC at his Senate health committee nomination hearing. Azar evaded the question by citing that certain "scientific and legal standards" must first be met by the sponsors of the product before the FDA can make the decision. Senator Lisa Murkowski (R-AK), who questioned Azar on the subject, affirmed her support for OTC access to OCs, maintaining that the prescription barrier makes them more expensive and less accessible. Working group member, Susan Wood, who previously served as Assistant Commissioner for Women's Health at the FDA and directed the FDA Office of Women's Health, was featured in the article below, pointing out Azar's lack of knowledge on the prescription-to-OTC switch process and discomfort with discussing contraception. Azar did show support for updating the OTC monograph system to make the process more efficient and less costly.

Inside Health Policy: [Azar sidesteps OTC contraception question, supports updating OTC monograph system](#). Please [contact Mary](#) if you have trouble accessing the article.

Massachusetts contraceptive coverage law

Last month, Massachusetts Governor Charlie Baker signed a contraceptive coverage bill into [law](#). It will require coverage for contraceptive drugs, devices, and products without co-pay and emergency contraception without a prescription. It will also require insurance plans to cover up to a 12-month supply at once after an initial three-month supply.

Boston Globe: [Obamacare or not, birth control in Mass. will stay free](#)

WBUR: [Countering Trump, Mass. swiftly passes new law ensuring access to no-cost birth control](#)

New Zealand pharmacist prescribing update

In February 2017, Medsafe, the medicine regulatory body of New Zealand, reclassified some OCs, allowing pharmacists to prescribe them to anyone over age 16 who has been prescribed a similar formulation within the last three years. Pharmacists must first complete a ten-hour training before they are certified to participate. [This article](#) from the *Manawatu Standard* profiles pharmacists' progress in prescribing OCs.

Closing the gender gap in tech through protecting women's health

Working group member Monica Harrington wrote an [op-ed](#) in *Crosscut* urging tech companies in Washington state to prioritize women's health in their insurance plans, including providing insurance coverage for OTC contraceptives. Tech companies and other private insurance providers can play a role in showing policymakers that support for women's access to reproductive health is a priority and build on the momentum of private and public insurance plans covering OTC contraceptives.

Statement of purpose sign-ons

We are pleased to highlight the organizations that have signed onto our [statement of purpose](#) within the last month. Please help us demonstrate the wide support that exists for making OCs available OTC in the United States. [Email Mary](#) if you would like your organization to sign onto the statement of purpose.

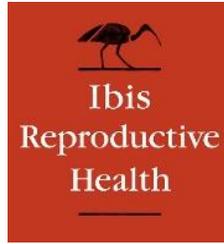
[Illinois Caucus for Adolescent Health](#)

[Jacobs Institute of Women's Health](#)

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

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