

Press Release:

National Cancer Institute (NCI) and University of Oxford Study Acknowledge Breast Cancer Risk of Hormonal Contraceptives (The Pill); Food and Drug Administration (FDA) Lags Behind

From the Contraceptive Study Group (CSG)

2023 March 28

The Contraceptive Study Group (CSG), a team of physicians, scientists and other experts who have been investigating the side effects of contraceptives, is pleased to announce that their findings on the breast cancer risks of hormonal contraceptives have been confirmed by a recent [University of Oxford \(UK\) and Adelaide Medical School study](#). Breast cancer is the second most common cancer in women (after skin cancers) and accounts for over 40,000 deaths each year in the USA alone. The study confirms an increase in risk for progesterone-only contraceptives while acknowledging the risk for combined hormonal contraceptives. [The NCI](#) recently updated their assessment of cancer risk for hormonal contraceptives and state, “overall, women who had ever used oral contraceptives had a slight (7%) increase in the relative risk of breast cancer compared with women who had never used oral contraceptives. Women who were currently using oral contraceptives had a 24% increase in risk ....” The CSG submitted a [citizen petition](#) on May 9, 2019 asking the FDA to have the prescribing information on hormonal contraceptives updated to include previously unacknowledged risks, including breast cancer. On May 17, 2022, the FDA posted a [partial response](#) to the petition on the website for the petition<sup>1</sup>. This response only considered the risk for breast cancer and noted that, “there could be a slight increase in the risk of breast cancer among current users with longer duration of use” but denies longer term effects. Based on analysis of dozens of scientific studies from all over the world the CSG estimates that the risk of breast cancer is increased with any use of hormonal contraceptives and urges the FDA to further update the prescribing and patient information, including a boxed warning, in line with the best scientific evidence.

### **Additional Information:**

The [National Cancer Institute](#) acknowledges an increase in the risk of breast cancer for both “ever users” (those currently or previously on hormonal contraceptives) and current/recent users. Specifically, they state:

**Breast cancer:** An analysis of data from more than 150,000 women who participated in 54 epidemiologic studies showed that, overall, women who had ever used oral contraceptives had a slight (7%) increase in the relative risk of breast cancer compared with women who had never used oral contraceptives. Women who were currently using oral contraceptives had a 24% increase in risk that did not increase with the duration of use. Risk declined after use of oral contraceptives stopped, and no risk increase was evident by 10 years after use had stopped (4).

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<sup>1</sup> Note that the Contraceptive Study Group was not informed of this response, but only found it when researching potential further action almost a year later.

A 2010 analysis of data from the Nurses' Health Study, which has been following more than 116,000 female nurses who were 24 to 43 years old when they enrolled in the study in 1989, also found that participants who used oral contraceptives had a slight increase in breast cancer risk (5, 6). However, nearly all of the increased risk was seen among women who took a specific type of oral contraceptive, a "triphasic" pill, in which the dose of hormones is changed in three stages over the course of a woman's monthly cycle. An elevated risk associated with specific triphasic formulations was also reported in a nested case-control study that used electronic medical records to verify oral contraceptive use (7).

In 2017, a large prospective Danish study reported breast cancer risks associated with more recent formulations of oral contraceptives (8). Overall, women who were using or had recently stopped using oral combined hormone contraceptives had a modest (about 20%) increase in the relative risk of breast cancer compared with women who had never used oral contraceptives. The risk increase varied from 0% to 60%, depending on the specific type of oral combined hormone contraceptive. The risk of breast cancer also increased the longer oral contraceptives were used.

Since May 2022, the FDA has required manufacturers to update the prescribing information and Patient Package Insert with the following information:

**Patient Package Insert:**

Do birth control pills cause cancer?

It is not known if hormonal birth control pills cause breast cancer. Some studies, but not all, suggest that there could be a slight increase in the risk of breast cancer among current users with longer duration of use.

If you have breast cancer now, or have had it in the past, do not use hormonal birth control because some breast cancers are sensitive to hormones.

**Prescribing Information**

**Warnings and Precautions**

Malignant Neoplasms

Breast Cancer

DRUG is contraindicated in females who currently have or have had breast cancer because breast cancer may be hormonally sensitive [see Contraindications (4)]. Epidemiology studies have not found a consistent association between use of combined oral contraceptives (COCs) and breast cancer risk. Studies do not show an association between ever (current or past) use of COCs and risk of breast cancer. However, some studies report a small increase in the risk of breast cancer among current or recent users (<6 months since last use) and current users with longer duration of COC use [see cross reference to appropriate section in Adverse Reactions, e.g., Postmarketing Experience (6.2)].

The CSG submitted summary information from 11 cohort studies (considered the most rigorous epidemiological studies) which looked at the risk of “ever use” of hormonal contraceptives, of which 8 showed a statistically significant increase in risk, 2 failed to reach statistical significance, and one showed a statistically significant decrease in risk. There were also 20 case control or similar studies which evaluated “ever use” of hormonal contraceptives and of these 12 showed a statistically significant increase in risk, 7 failed to reach statistical significance, and one showed a statistically significant decrease in risk.

Overall, the Contraceptive Study Group agrees with the NCI that the most scientifically sound studies show an increase in risk for breast cancer for “Ever Use” of hormonal contraceptives, although the CSG believes the risk is higher than that acknowledged by the NCI. The CSG disagrees with the FDA’s conclusion that “ever use” has no impact on the risk of breast cancer. In particular, the CSG notes that the FDA selected studies to include in its analysis that minimize the risk of breast cancer with hormonal contraceptives while ignoring other, larger and better quality studies. The CSG urges the FDA to reflect the conclusions of the best studies in the prescribing information and in the Patient Package Inserts for hormonal contraceptives.

Breast cancer represents a small portion of the overall petition that the CSG submitted nearly four years ago. The CSG urges the FDA to acknowledge the remaining evidence provided in the petition showing links to a wide variety of severe and chronic ailments. The inclusion of these diseases in Patient Package Inserts is necessary for women looking to make an informed decision.

Respectfully,

The Contraceptive Study Group

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