

A Note from the President

By Angela Lanfranchi MD



About 2 years ago I was invited to join the Contraceptive Study Group initiated by Dr. William Williams to do research on the adverse effects hormonal contraceptives. The purpose was to do a formal Petition to the FDA requesting modifications to the presently provided information from the manufacturers. Referred to as “the package insert,” this information accompanies the drugs you take home from the pharmacy. The information in very fine print usually comes on thin paper in a tightly folded wad in the package containing your prescription drug. This then unfolds into a HUGE sheet with “medicalese” and chemistry formulas on the front and back that no one can read or understand without a great deal of effort or a PhD in a scientific field. In order to grab your and your doctor’s attention, the FDA will sometimes mandate a “Black Box Warning” on that HUGE sheet which is literally a box of very thick **black** lines around some really important information so maybe, just maybe, someone will read it. It usually contains a warning about a life threatening effect of the drug, so serious the patient and doctor should become aware of it before ingesting it. The HUGE sheet usually gets immediately recycled with the paper packing the drug came in and remains unread. Our Petition recommended 6 **Black Box** warnings and one product to be removed from the market as it facilitated the male to female transmission of the AIDS virus, HIV. That drug is Depo-Provera, which is used by injection every three months for contraception.

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Oral Contraceptives Found to Shrink Hypothalamus

Study may have discovered the biologic mechanism for mood & behavioral changes experienced by women on the Pill

By Angela Lanfranchi

MD In a December 4th, 2019 press release, the Radiological Society of North America (RSNA) announced the results of a study. The lead author was Dr. Michael Lipton M.D., PhD., who is a professor of radiology at Albert Einstein College of Medicine and medical director of the MRI services at Montefiore Medical Center in New York. The study was partly funded by the National Institutes of Health. His study confirmed that current oral contraceptive pill use is associated with a smaller hypothalamus. According to the release, it is “The first study to examine the effects of oral contraceptives on the structure of the living human hypothalamus . . .” Referring to the hypothalamus, Dr. Lipton stated, “There is lack of research on the effects of oral contraceptives on this small but essential part of the living brain.” This lack of research was concerning because a 2018 report from the Centers for Disease Control and Prevention’s National Center for Health Statistics reported that from 2015-2017 about 6 million women in the U.S. reported current use of the oral contraceptives. Also, 88% of women have used hormonal contraception and they are used in preteens and teens.



The study found that women taking birth control had a significantly smaller hypothalamus volume as measured quantitatively by MRI. Smaller hypothalamic volume strongly correlates with depression and is associated with greater anger. The study’s finding may well have discovered and the biologic mechanism for some well documented adverse effects hormonal contraceptives: decreased libido, mood disorders, depression, suicide attempts and suicide.

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Save the Date: 10th Golf Classic on June 5, 2020

This coming Spring, Bob Gerling will be organizing BCPI’s 10th Golf Classic on Friday, June 5th. It will be held at the Cranbury Golf Club near Princeton, New Jersey. We welcome golfers to participate in a round of golf and non-golfers to join us for dinner from 5:00-7:00 PM in the Club House. If you would like to participate or join us for dinner, information about the golf course and registering for the tournament can be found at: <http://www.dixongives.com/breastcancer>. If you have more questions you can email us at info@bcpinstitute.org. This event allows us to connect personally and we look forward to seeing you if you can come and are in the New York Tri-State area. It’s about an hour drive from New York City not far from the New Jersey Turnpike.



This year’s honoree is Dr. Joel Brind, Professor of biology and endocrinology at Baruch College of the City University of New York. A co-founder of BCPI in 1999, he no longer serves BCPI in an official capacity, however he continues to be of great service writing articles for the “BCPI Report” and reviewing prepublication manuscripts of many BCPI materials. He continues to do original research and contribute to the medical literature. Published in 1996, he is the first author of the first meta-analysis of the abortion-breast cancer link studies which demonstrated that induced abortion was a risk for breast cancer.



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I have to admit I didn't think the petition would do much good. After all, the World Health Organization had acknowledged the Pill was definitely a cause of human breast cancer for the last 15 years. Yet doctors and patients seemed to be unaware of this. Either the information was disregarded because the risk was low or because the Pill was thought to be so essential that women could not have birth control without it. Yet every woman who gets breast cancer wants to know what their risk factors were that might have contributed to the development of their cancer. The truth is this: a woman might have every risk factor known to man yet her cancer may have been caused by a random, sporadic, unavoidable mutation that occurred when a breast cell replicated its DNA during the follicular phase of her normal menstrual cycle. (That is one reason why the more menstrual cycles a woman has in her life, the higher her breast cancer risk.) She could not have avoided that mutation that led to her cancer. However, we can't deny that there are some breast cancers caused by hormonal contraceptives. According to a 2011 study by Parkin published in the British Medical Journal, 14.9% of women under age 49 get their breast cancer because they took hormonal contraceptives. This is known as an attributable risk. That means last year there would have been more than 8,000 fewer breast cancer cases in young U.S. women if none had taken hormonal contraception. Over 6,000 of those women have young children or adolescents still in their care. Breast cancer in young women strikes at the heart of the family, especially single parent families. Breast cancer patients may no longer be able to care for their children during treatment and some will die of their disease. That doesn't seem like a lot of women out of a population of over 150 million women in the country. Yet that's a number that happens year after year. The Pill has been on the market for 60 years.

The FDA accepted the Petition in June 2019. In a letter dated October 31, 2019, the FDA wrote: "The FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials." The correspondence can be read in full online at links below.

So that all that good information would not go to waste while waiting for the FDA determination, I printed out some copies of the 98-page FDA Petition. The Petition was informative and made me realize things I had never considered. I learned so much from my colleagues in the group. I thought it would be useful for doctors to have as a reference. Those that received copies said it was useful not only for the information it provided. Some also used it in self-defense when challenged by their employers to justify being non-prescribers of hormonal contraceptives especially when less harmful drugs could achieve the same goals or other methods of family planning were available.

I also wanted to share that information with those not in medical fields. To that end, I placed the FDA Petition on our website, www.bcpinstitute.org, under the Resources tab below News and Publications. I also incorporated the Petition into a new book called *Health, Hormones and Contraception*. I hope the book will help women understand their reproductive biology and the ways their choice of contraception can affect their health. *Health, Hormones and Contraception* will be available as a hard copy and online as well. In it, I explain the meaning of those three terms in the title, a woman's reproductive biology and answer the commonly asked questions of me about hormonal contraception over my 33 years in a surgical practice. Also in the book are the complete FDA Petition and other medical references used to answer the questions posed.

The book also provides links to the FDA Petition including this one: <https://www.regulations.gov/comment?D=FDA-2019-P-2289-0001>. This will allow you to directly comment on the Petition to the FDA.

You can also read the comments that have already been posted at <https://www.regulations.gov/docket?D=FDA-2019-P-2289>. Some are from parents who lost their daughter to an adverse effect of the Pill and are heartrending.

I hope you will add your comments to the FDA Petition as well.

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The hypothalamus is a very important central brain structure as it regulates many vital functions in people including mood, menstrual cycles, libido (sex drive), appetite, sleep cycles, heart rate and temperature. Well-known to physicians who prescribe oral contraceptives or treat psychiatric disorders are the facts that oral contraceptives affect mood and decrease libido. Women who have taken the Pill also know this well. A Millennial adage is "I started the Pill because I started having sex. Now I'm on the Pill and I don't have sex."

A 2017 Danish study of nearly half a million women found that women taking all hormonal contraceptives (including oral contraceptives) were at increased risk for suicide attempts and suicides. The women studied had no prior psychiatric diagnosis or antidepressant use. The risk of suicide attempt peaked just 2 months after starting use. Interestingly, it was found that different contraceptives had different risks and seemed to correlate with the doses of hormones in the contraceptives. The patch had the highest increase in risk of suicide attempt at 228% while oral contraceptives had the lowest at 97%. The patch is known to result in about a 60% higher estrogen level in the blood than oral contraceptives when taken at a similar dose. As oral contraceptives are ingested, they must first pass through the liver before getting into the circulation for its effect. In contrast, the estrogen in the patch goes through the skin directly into the circulation. The studies also found that the overall risk of suicide attempts were higher with the contraceptive which contained the highest dose of ethinylestradiol, a synthetic steroid drug which stimulates estrogen receptors.

It is well established in the field of evolutionary psychology that oral contraceptives change the behavior of women using them and influence their relationships with men. For example, women become more jealous in their relationships with men than women not on hormonal contraception. A 2011 study by Cobey, "Hormonal birth control use and relationship jealousy: Evidence for estrogen dosage effects" also found the higher the synthetic estrogen dose in the contraceptive, the more self-reported jealousy a woman felt in her

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China Confirms Induced Abortion Is A Major Risk Factor for Breast Cancer

Increasing breast cancer incidence and deaths in China spark development of new risk model

By Angela Lanfranchi MD

This past year in 2019, a new breast cancer risk model was developed to evaluate Han Chinese women. These researchers found abortion to be the most impactful risk factor, higher than even age at first birth.

Risk models contain questions posed to the woman being evaluated in order to create a score which determines the likelihood of breast cancer development within one or more time frames. The Han are the largest ethnic group in China accounting for 92% of the population. The authors from Shandong University in Jinan published their results in the journal, *BMC Cancer*. The authors believed the Gail Risk model was not useful for them. The Gail Risk model used commonly in the United States was not appropriate for their population as it was developed on mostly Caucasian women and contains questions such as the number of breast biopsies a woman has had and if any results had atypical (abnormal) cells. [Breast biopsies correlate with risk because non-cancerous (benign) biopsies that make a lump or cause mammographic changes are typically due to proliferative breast conditions that are commonly found in patients with breast cancer.] The authors stated that "... because biopsies are not widely used in China (especially in rural areas)..." it is important for a new model to be made for Chinese women. The process they used determined which risk factors were the most impactful for Chinese women.



To identify risks they did two studies. They did a prospective study: a group of 18,681 women who completed a questionnaire in 2008 were followed for 7 years. They also did a case-control study in which they compared risk factors of women diagnosed with breast cancer and those that were cancer-free. After these two studies they identified 7 key risks to be used in their new risk model: 1) BMI, a measure of obesity, 2) a "life satisfaction score" based upon satisfaction with housing, income, health, marriage, medical care and neighbors, 3) family history of breast cancer, 4) the number of abortions, 5) age at first birth, 6) history of benign breast disease such as cysts and 7) age. The Gail Risk also uses age, family history and age at first birth.

The scientists found the abortion risk factor to be the most impactful on breast cancer risk: 1 or 2 abortions increased breast cancer risk 151% and 3 or more abortions 379%. The second most impactful was age at first birth. Compared to giving birth before the age of 25, if a woman's age at first birth was 25-29 years old her risk increased 89%; if she was 30 or more years old her risk increased 259%. These results were statistically significant with 95% certainty that they could not have resulted from chance alone.

Abortion history is prevalent in China as it is used as reinforcement of their recently relaxed one-child policy enforcement. Due to falling birth rates and female infanticide in order to have a male child, China is now encouraging earlier marriages and more than one child through new social policies. The one-child policy has caused social disequilibrium with lack of brides and resultant human female trafficking. Hopefully, with fewer abortions and earlier births, breast cancer incidence will start to decline in China and male and female birth will re-equilibrate.

Breast cancer risk models are created so that a woman can have a calculation of their personal risk of developing breast cancer. They provide the information needed for screening. If they are of average risk, they are able to follow the general screening recommendations for their age such as when to start screening, what method to use and how often the screening should be. If a woman is found to be at higher risk than the general population, she may have need frequent screening with additional methods or even drugs and surgery to reduce her risk. Screening allows for the earliest detection of breast cancer and the highest possibility of cure.

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relationship. A 2012 study in the journal *Hormones and Behavior* titled "Hormonal contraceptive use and mate retention behavior in women and their male partners" revealed that the higher the dose of the synthetic estrogen drug such as ethinylestradiol in the contraceptive, the more frequent the mate retention behaviors in the female and male. (Mate retention behaviors can range from trying to be more physically attractive and gift giving to verbal threats and physical violence. They are measured with a standard validated questionnaire, The Mate Retention Inventory, or MRI-SF, used in the field of psychology for behavioral relationship studies.) These results are similar to the 2017 Danish study previously discussed as all these studies found behavioral changes related to levels of synthetic estrogen drugs.

It may well be that the smaller volume of the hypothalamus in women who take oral contraceptives is responsible for the psychological changes found in women who are taking hormonal contraception. Hormonal contraceptives have many adverse effects on women's lives besides breast cancer. The study found no significant changes in women's cognitive ability, i.e. reasoning, problem solving or learning.

However, the adverse effects provide ever increasing reasons why women should abandon their use of oral contraceptives as a method of family planning and choose a method that doesn't imperil their lives or relationship with those they love. Alternative family planning methods are discussed in *Health, Hormones and Contraception*, a new book to be published soon.