'Petition on Hormonal Contraceptives': The Real Effects of Hormonal Birth Control

By Susan Ciancio

Breast cancer. Cervical cancer. Depression. Mood disorders. Suicide. Multiple sclerosis. Ulcerative colitis. Venous thromboembolism. Inflammatory bowel disease. Systemic lupus erythematosus. Cystitis. Crohn's disease. Urogenital effects. Cardiovascular events. Increased chance of HIV transmission.

Your doctor rattled off those words like he was calling roll in a classroom. But each one made you cringe a little more than the last. You could feel your eyes widening as the list grew. Side effects—for a drug you don't even need, for a drug not designed to alleviate a sickness. You look at him dubiously, as if maybe he's joking. *These can't all be side effects from one drug*, you think. But the look on his face tells you that he is not joking. In fact, he is very serious. And luckily for you, he cares enough about you to tell you what could happen if he prescribes the drug you're asking for. You start to think to yourself: I don't want to do that to my body. I value my health too much. I respect my body more than that.

You wonder why you never heard any of this before, and you realize you're going to have to rethink your desire for hormonal birth control.

The Petition

In June 2019, 10 doctors and researchers who had formed a Contraceptive Study Group published a document entitled *Petition on Hor*- *monal Contraceptives.* This document evaluated existing literature and synthesized studies on hormonal birth control in order to present information on their side effects in one comprehensive document. The Contraceptive Study Group's goal was to not only warn potential users, but also to petition the government to add black box—or warning—labels onto the boxes of contraception and to include warnings on patient-related information so that women know and understand the risks of the chemicals they put into their bodies. This article serves as an overview of just some of the major findings and of the information this group desperately wants to put forward for all to know.

The members of the Contraceptive Study Group understand the damage hormonal contraceptives do to women, to the babies they may carry, and to the families who love them. That is why they undertook the daunting task of reading, interpreting, compiling, and then disseminating the information they found. In all, this petition cites 230 outside sources—not counting those related to the environmental impact. This petition was not only a labor of love and compassion for their fellow human beings but also serves as a wake-up call to people who unknowingly—or knowingly—ingest these harmful chemicals.

Millions of women take hormonal birth control or receive contraceptive injections without any idea about the poison they're putting into their bodies. According to the <u>petition</u>, "Based on data from the Guttmacher Institute, a conservative estimate of 11 million women aged 15-44 in the US take some form of hormonal contraceptive each day. A 2015 study reports that about 21 percent of women of reproductive years are using some form of hormonal contraceptive, which equates to about 13 million women (Daniels 2015)."

In addition, millions of babies die when these contraceptives thin the lining of the uterine wall, thus preventing the baby from implanting.

Hormonal contraceptives have been on the market for over 50 years, yet the scope of the devastation and health ramifications they have caused can never be known. Some women don't even realize that the causes of the health problems they face may be contraception. If this petition succeeds in its intent, pharmaceutical companies will have to disclose these side effects.

The petition begins by listing the side effects of combined estrogen-progestogen contraceptives (COCs). Many are mentioned in the first paragraph above. COCs include oral, intravaginal, and transdermal formulations. The petition lists the brand names of all of these—in six pages.

According to the team, progestogen-only contraceptives (POCs) "have not been extensively studied, but one large registry study did show a significantly increased risk of breast cancer with use of POCs."

Furthermore, the International Agency for Research on Cancer (IARC) classifies COCs as Group I carcinogens, meaning they can cause cancer in humans.

Recommendations

The petition recommends that the government "remove from the market the injectable contraceptive Depot Medroxyprogesterone Acetate (DMPA; Depo-Provera) based on conclusive evidence that it facilitates the transmission of HIV from men to women." It then recommends that black box warnings should be added for the following diseases and conditions: breast cancer, cervical cancer, inflammatory bowel disease, systemic lupus erythematosus, depression and suicide, venous thrombosis, and cardiovascular events. In addition, safety information should be added to advertisements and patient-related materials about multiple sclerosis, bone fractures, body mass effects, and urogenital problems.

Countless women suffer the side effects of hormonal contraception. Countless women feel duped by healthcare providers, by pharmaceutical companies, and by organizations that tout the benefits of COCs. Rarely do they hear of these side effects—side effects that can appear after long-term use, after a few months, or even after just a few short weeks.

In conjunction with the petition, the public is asked to post comments or stories to this <u>site</u> in order to encourage the government to add warnings to contraceptive labels. Many of these comments reference tragic and heartbreaking stories of loss—loss of life, loss of health, and loss of autonomy.

You might wonder why many physicians don't warn their patients about these side effects. Dr. Ken Stone offers <u>some insight</u>:

It is common practice that physicians do not discuss any significant adverse effects of oral contraceptives or require an informed consent. Some colleagues have said to me that they do not want to say anything that would deter them from using the pill. Standard adverse effects in formularies for prescribed contraceptive medicines usually do not mention the most severe ones like pulmonary embolus, stroke, breast cancer, liver disease, etc. This petition for removing certain contraceptives from the market, listing those adverse effects that should have black box warnings in prescribed contraceptives, and those that need additional safety warnings in prescribed contraceptives provide[s] more than adequate research data to require the actions requested. As a family practice physician for the past 41 years, I believe the scandal of not informing women of the known side effects of contraceptives is an egregious injustice and needs immediate correction.

The members of the Contraceptive Study Group believe that the public should know the truth. Throughout the next several pages, we will discuss some of the findings and data they presented regarding many of the major side effects of hormonal contraception. To read the petition in its entirety, and to see the comprehensive list of side effects, visit the <u>petition's site</u>.

HIV Transmission

Depo-Provera, or DMPA, is an injectable contraceptive that is administered quarterly. However, according to the study group: "Evidence began emerging in the 1990s, which has become compelling in recent years, that DMPA is unique among contraceptives in its property of facilitating the transmission of HIV."

How is this so?

According to research, DMPA has an immunosuppressant quality. It binds to the glucocorticoid receptor of human leukocytes, which, in layman's terms, means that it represses the woman's innate immune responses and allows for an increase in HIV replication. Thus, when an infected man has intercourse with a woman taking DMPA, her compromised immune system cannot fight off the disease.

Because of this, the authors want DMPA taken off the market.

Breast Cancer

According to the petition, there are 1.7 million cases of breast cancer diagnosed every year. It is the most common form of cancer among women in developed countries and accounts for 20% of cancers in females.

The International Agency for Research on Cancer classifies COCs as Group 1 carcinogens. That means they can cause cancer in human beings. Studies have long shown the link between breast cancer and COCs. The New England Journal of Medicine published an article in 2006 that found that COCs increase the risk of breast cancer. That same year, the *Mayo Clinic Proceedings* (a medical journal sponsored by the Mayo Clinic) published a meta-analysis that confirmed the findings that COCs increase the risk of premenopausal breast cancer.

According to the Contraceptive Study Group, "Studies that looked at recent use (within 1–5 years) or current use of COCs in premenopausal women showed the most dramatic increased risk for breast cancer." The most significant study found that women between the ages of 20-49 who had used COCs "within a year had an increased risk of breast cancer."

Other studies corroborate these findings as well. Most found that women who used COCs for a year or more had a higher risk of breast cancer. A Danish study found that a woman's risks increased even after she discontinued use if she had used COCs for five or more years.

The comments site offers many stories from women who have suffered from breast cancer and from the doctors who have treated them. Included among them are these:

Anthony Vigil, MD, FACS, says:

As a general surgeon, me and my partners ask our breast cancer patients about OCP

[oral contraceptive pills] use since our best cancer textbooks describe an increased risk of breast cancer with OCP use. It is ethically imperative that women are made aware of the risks of ingesting hormones into their bodies.

Anna Poynter says:

At age 31, I found a small breast lump. I went to more than one doctor, but the last one I saw was the head of the UCSD Cancer Institute, a Dr. Barone, in San Diego, where I lived at the time. He told me that it was small, movable and I didn't have any pain but that I should GET OFF THE PILL. 19 years later that very same lump grew and became malignant, and I ended up having a mastectomy.

An anonymous writer <u>says</u>: "Recently diagnosed with breast cancer; I was on the pill for 10 years."

The authors recommend that a black box warning be included with COCs, along with warnings on patient-related materials, so that women understand the risks they face.

Cervical Cancer

According to the petition, approximately 260,000 women in the United States have cervical cancer. The American Cancer Society claims that there will be about 14,000 new cases this year alone. Research has shown that there is an increased risk of cervical cancer associated with COCs and that the risk increases for women currently taking hormonal birth control. In addition, the risk increases with the length of time the woman has taken the COCs.

The risk also increases if the woman has tested positive for HPV—the human papilloma virus.

The authors recommend both a black box warning and a warning on patient-related materials.

Depression, Mood Disorders, Suicide

According to the study group, "The largest study of incident depression and use of anti-depressant medication (Skovlund 2016) indicates significantly increased risks for both COCs and POCs for both outcomes. The same group studied for suicide attempts and suicides (Skovlund 2018). Elevated risks were seen, and this was the case for both COCs and POCs. The recent NCHA study (Gregory 2018) showed a similar trend."

The authors claim that their research has shown an "increased risk for depression, suicide risk, and suicide within 3 months of beginning to use the drugs and tapering off after 6 months, partly due to attenuation of symptoms, partly due to discontinuation due to adverse effects."

The comments section of the website paints a dismal picture and offers evidence that these hormones cause new mental health problems and exacerbate existing or latent ones.

Julie Baltz, a family practice clinician who has practiced medicine for over 20 years, states that <u>she has seen the psychological harm</u> caused by hormonal contraceptives. She wrote:

> Even more subtle and more underreported are the psychological effects. These patients simply state "I didn't feel right" and often think that there something wrong with them that they don't tolerate this type of medication. I've seen insomnia, anxiety, depression, anhedonia, anorexia, and poor libido directly improved within my clinical office by discontinuing a combined OCP.

Another person, known only as TF, <u>wrote in to</u> <u>say</u>:

In 2011 I was prescribed hormonal birth control to "fix" a very irregular cycle. Three months later I started to struggle with crippling fatigue, loss of appetite and disinterest in everything except sleeping. I was shortly after that diagnosed with Major Depressive Disorder, and still to this day have to be on medication to remain functional. I still struggle with my energy levels, unfortunately medication can't cure depression and make it disappear. My doctor and I both believe that the hormonal birth control was likely a trigger to a predisposition for Major Depressive Disorder.

A woman who wishes to remain anonymous <u>stated</u>:

In my early twenties I was prescribed birth control pills. The first cycle I took the pills as prescribed. I began to feel depressed, anxious, crying daily, with mood swings. Prior to beginning the oral contraceptive pills, I had none of these symptoms. After completing the first 2 weeks of the medication packet, I called the nurse practitioner at the OB/GYN clinic that I originally got the prescription. She told me that the changes in my mood, depression, and anxiety among others, could not be due to the new medication, that it must have just been life. She changed me to a lower dose contraceptive pill. After three weeks of taking the second prescription pack as directed I decided to discontinue use of oral contraceptives due to the side effects. *I had gained 15 pounds and felt terrible.*

The site is filled with story after story of people who have suffered—mentally and physically because of these drugs. The authors want a black box warning about this side effect and warnings on patient-related materials.

Body Mass

While studies have varied regarding weight increase in women who use COCs, the strongest data found that levonorgestrel-releasing IUDs do, in fact, affect body mass. The authors stated that "a significant increase in % fat mass with a corresponding decrease in % lean body mass was observed in both studies where these were measured."

Women have found this side effect all too real. For example, a woman who wishes to be anonymous <u>said</u>:

> When I was taking hormonal birth control (HBC) I underwent a massive weight gain. From 120 lbs. to 155 lbs. That's almost adding 30% to my body weight! I also suffered with severe stomach cramping, constant discomfort, constipation and diarrhea. My doctor diagnosed it at IBS. I was only on HBC for 8 months and got pregnant while taking it. I stopped taking it upon pregnancy and have never touched the stuff again!

The authors believe that all patient-related materials and advertising (print, radio, etc.) should convey information about this risk to the consumer.

Urogenital (Urinary and Genital) Effects

The authors found evidence of several different kinds of urogenital problems in women. These include interstitial cystitis (a condition that causes bladder pain and pressure), bacterial infections, urinary tract infections, vulvovaginal candidiasis, vaginal dryness, female sexual dysfunction, and more. They state that the risk increases for adolescents and if the woman uses COCs for at least two years.

A woman who wishes to remain anonymous experienced a whole host of problems, including urogenital. She <u>said</u>:

I was put on birth control by my parents when I was only 15 years old after a sexual assault incident. I then continued it for another 5 years before I began to question it. In that time frame I experienced extreme weight gain and loss from one pill to another, was diagnosed with bipolar disorder because of my manic depression and severe mood swings (I am not bipolar), experienced a miscarriage, developed cysts in my breasts, had continuous pregnancy symptoms (including morning sickness every day), and had frequent UTIs and yeast infections. No one ever associated any of my problems, other than the breast cysts, to my birth control pills. It wasn't until I discontinued the use once learning of the cysts that I began to feel normal and realized the association between my symptoms and the pill.

The authors believe that all patient-related materials and advertising (print, radio, etc.) should convey information about this risk to the consumer.

Venous Thromboembolism, Atherosclerosis, and Cardiovascular Events

Venous Thromboembolism

A venous thromboembolism (or VTE) is a condition in which a blood clot forms in a vein, most often in the leg, arm, or groin, and then lodges itself in the lung. This is an extremely dangerous health problem that can cause death. Even the American Heart Association <u>website agrees</u> that COCs can cause a VTE: "In women, pregnancy and the use of hormones like oral contraceptives or estrogen for menopause symptoms can also play a role."

The comments regarding this side effect address the tragedies that have befallen women and families as a result of hormonal birth control. For example, Carol Pepin <u>wrote</u> about the loss of her daughter: My 19-year-old daughter Shelby Pepin . . . died. Shelby was very athletic, did not smoke, and had no history of a blood disorder. The coroner's report confirmed that Shelby had died from a pulmonary embolism. She had a DVT [deep vein thrombosis] behind her left knee that traveled to her lungs causing her bilateral embolism. The coroner also confirmed that her DVT was caused by her birth control the NuvaRing. Shelby had been on the NuvaRing for 18 months.

Joseph West has a <u>similar story</u>:

Our daughter died at age 29 in the Intensive Care Unit of her local hospital where she had been transferred after presenting herself at her local walk-in clinic. Her death was five weeks to the day after getting married and one day before [her] scheduled departure on a delayed honeymoon cruise. The autopsy report stated that she had "bilateral pulmonary thromboemboli" with a thrombus present in the left popliteal fossa. She had been using NuvaRing at the time of her death [which] had been removed at the walk-in clinic prior to transport to the hospital. . . . The [ICU] doctor stated that she believes that hormonal birth control was a significant contributor to the death of our daughter.

Kimberly Phipps-Nichol shared her <u>personal</u> <u>story</u> of survival:

Last year, at the age of 46, I was hospitalized with a cerebral thrombosis that was literally caught right before causing a stroke. The ER docs told me that if it had not been for the fact that the people I was with at the time of the event were trained to recognize the signs of stroke and called 911 for a stroke paramedic unit that arrived quickly, I would have been somewhere between a vegetative state and severely disabled. After countless CT scans and MRIs, along with a thorough study of my family history, the neurologist and hematologist teams determined it was the oral contraceptives that I was taking that had caused the thrombosis.

An anonymous <u>family physician</u> claims to have seen the negative side effects of contraceptives firsthand and tells of several cases, including her treatment of a young woman in her late 20s who went into a coma brought on by a pulmonary embolism. The only known risk factor was that this woman was taking hormonal birth control. In addition, a medical colleague of this doctor suffered a pulmonary embolism that was attributed to OCP.

Nancy Brockoff <u>wrote</u> to say that she had four friends, who were all young mothers, who died of blood clots related to hormonal birth control.

Atherosclerosis and Heart Disease

Atherosclerosis is a disease of the arteries caused by plaque. Arteries clogged with plaque lead to heart problems. Even as long ago as 1982, researchers understood and took interest in the fact that vascular disease and COCs were linked. According to the petition, these researchers "found that combination oral contraceptives (COCs) caused 'greater cell proliferation and incorporation . . . in both human arterial smooth muscle cells and dermal fibroblasts.' Smooth muscle cell proliferation is an integral feature of all atherosclerotic lesions (Bagdade 1982). In 2007, a presentation at the American Heart Association meeting described a study of 1,301 Belgian women, which showed that women had a 20 to 30 percent increase of plaque for every decade on COCs (Rietzschel 2007)."

Furthermore, the Danish Heart Association "released the results of a 15-year historic cohort study looking at thrombotic stroke and myocardial infarction, which observed over 1.6 million women. The results demonstrated that women taking COCs with ethinyl estradiol at a dose of 20 [micrograms] had a risk of arterial thrombosis that was 0.9 to 1.7 times higher than non-users, while those taking a dose of 30 to 40 [micrograms] had a 1.3 to 2.3 higher risk" (Lidegaard 2012).

The current black box warning about thrombotic events mentions smoking and age, which the authors believe misleads the consumer into thinking she's safe if she doesn't smoke or if she's younger than 35. They want the warning amended to read: "Warning: Increased risk of serious cardiovascular events including blood clots." Additionally, they request warnings on all advertising and patient-related materials.

Environment

The synthetic hormones that women take are continually released from their bodies through their waste products. When researchers noticed <u>changes in the aquatic environment</u>—especially in fish—they began conducting studies to determine the cause of these changes. What they found astounded them.

The Contraceptive Study Group explained:

EE2 [the synthetic estrogen ethinylestradiol] is metabolized in the liver undergoing first pass metabolism, but ~6% of the administered dose appears as untransformed EE2 in the urine and ~9% in the feces (Stanczyk 2013)....Even at low concentrations, these compounds can act as potent endocrine disruptors, affecting the growth, development, and reproduction of exposed aquatic organisms (Tyler 1998, Larsson 1999).

While wastewater treatment plants have the ability to filter out many chemicals and pollutants, they cannot filter out EE2.

Studies have found that these synthetic chemicals cause changes in male fish. A 1995 paper PAGE 8

found that male fish in nearly 30 rivers throughout Britain had become "feminized" by these pollutants.

The Contraceptive Study Group also referenced a seven-year long study of the effects of EE2 on Canadian lakes. In that study, researchers approximated the amount of EE2 that would reach the waterways from a town of 200,000 people. They immediately saw the feminization and transgendering of male fish and a "near extinction" of the population of the fathead minnow there. Once the researchers stopped adding EE2 to the water, the population of minnows returned to normal.

We find further evidence in a study that looked at the fish populations near three Colorado sewage treatment plants. There, researchers found a significant difference between the fish upstream of the plant and those downstream. They stated:

The fish in the upstream locations enjoyed a balanced 1:1 female-to-male sex ratio. Downstream there were five female fish for every one male, and twenty percent of the reduced male population demonstrated intersex characteristics, such as eggs in their testes and the presence of vitellogenin, an egg yolk protein normally found only in fertile females. The consequences also appeared to ascend up the food chain in a measurable way, specifically with the feminization of trout, mink frogs and green frogs (Parke 2009). Both the predicted and the measured concentrations of EE2 in the US, including effluent of waste water treatment plants, surface water, or ground water, exceeds the predicted no-effect concentrations on fish populations (Kostich 2013).

Conclusion

In addition to these diseases and the pollution in the environment, the economic costs from these side effects and their resultant diseases/ health problems to the patient and to the community are in the billions.

This article touched upon some of the most egregious side effects. To read the full list of side effects and the studies referenced, to read all of the comments, or to add your own comment, visit regulations.gov/document?D=F-DA-2019-P-2289-0001.

This health crisis affects us all. Whether you are male or female, elderly, middle aged, young, a mother, or a father, hormonal birth control does affect your life in some way because these hormones affect your wives, your mothers, your sisters, your cousins, your best friends, the environment, and even your dinner table. It's time to speak up and tell the government that women must know the truth. It's time to help women understand that their health is more important than a drug that can alter their body and mind. Synthetic hormones and their deleterious effects leave a lasting impact and crush our society.

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