

## HORMONAL CONTRACEPTIVES AND “EMERGENCY CONTRACEPTIVES”

### Prevalence of Contraception

According to a June, 2014 report by the Alan Guttmacher Institute<sup>1</sup>:

- Virtually all women (99%+) aged 15-44 who have ever had sexual intercourse have used at least one contraceptive method.
- Some 62% of all women of reproductive age are currently using some method.
- Some women do not need a method because they are infertile, are pregnant, postpartum or trying to become pregnant, have never had intercourse, or are not sexually active.
- Eleven percent of women at risk for unintended pregnancy are not currently using any contraceptive method.

The same report lists the following contraceptive methods and failure rates.

<u>Method</u>	<u>% of Users</u>	<u>Failure Rate* (typical user)</u>
Pill	27.5	9.0
Tubal Sterilization	26.6	0.5
Male Condom	16.3	18.0
Vasectomy	10.0	0.15
IUD	5.6	1.0**
Withdrawal	5.2	22.0
Injectable	3.8	6.0
Vaginal Ring	2.2	9.0
Patch	0.7	9.0
Implant	0.5	0.05
Fertility Awareness	1.1	24.0
Other Methods***	0.5	n/a

\* Proportion of women who will become pregnant over one year of use.<sup>2</sup>

\*\* Two types combined.

\*\*\* Includes emergency contraceptives, female condom, spermicides and sponge.

***Note:** The above failure rates differ by demographic group. For example, poor, cohabiting teenagers would have higher Pill failure rates.*

## HORMONAL CONTRACEPTIVES

### What Are They?

Hormonal contraceptives were first available in pill form in 1960. They may now be taken by mouth (“The Pill”), implanted into body tissue (“The Rod”), absorbed through the skin (“The Patch”), injected under the skin (Depo-Provera), dispensed from an intrauterine device (Miranda), or placed inside the vagina (Nuvaring).

As the table above indicates, the pill, or oral contraceptives (OCs), are the most commonly used. According to the National Cancer Institute<sup>3</sup>: “Currently, two types of OCs are available in the United States. The most commonly prescribed OC contains two man-made versions of natural female hormones (estrogen and progesterone) that are similar to the hormones the ovaries normally produce. This type of pill is often called a ‘combined oral contraceptive.’ The second type of OC ... is called the minipill. It contains only a synthetic type of progesterone,” called progestin or progestogen.

“**Estrogen** stimulates the growth and development of the uterus at puberty, causes the endometrium (the inner lining of the uterus) to thicken during the first half of the menstrual cycle, and influences breast tissue throughout life, but particularly from puberty to menopause.”

“**Progesterone**, which is produced during the last half of the menstrual cycle, prepares the endometrium to receive the egg. If the egg is fertilized, progesterone secretion continues, preventing release of additional eggs from the ovaries. For this reason, progesterone is called the ‘pregnancy supporting’ hormone...’ since it provides a nutrient-rich endometrium for the developing human being to implant.

### **How Do Hormonal Contraceptives Work?**

In 2008, the Practice Committee of the American Society for Reproductive Medicine noted that in the wide variety of oral contraceptives available their “mechanisms of action are the same.” They either 1) inhibit ovulation (so no egg is released), 2) alter the cervical mucus (so that it is more difficult for the sperm to reach the egg), 3) and/or modify the endometrium, thus preventing implantation.<sup>4</sup>

It is to be noted that the last “mechanism of action” constitutes an abortion, since the developing human being already consists of some 100 cells, but cannot implant in the mother’s womb. However, the family planning/population control movement persuaded the medical community to redefine “pregnancy” as commencing only after implantation, so that hormonal contraceptives could be continued to be considered “contraceptives” – that is, as preventing pregnancy, rather than aborting an existing pregnancy, which they do (at least in some instances) and would be considered as doing under the original definition, which considered the woman pregnant from the time of conception (fertilization).

There are no scientific studies that have firmly determined the relative frequency with which these three mechanisms, (or some combination of them) occur. Hence, we do not know how many abortions can be attributed to hormonal contraceptive use. One finding suggests that with the use of combined birth control pills (estrogen and progesterone), fertilization occurs, but implantation fails in from 1.7% to 28.6% of the time per cycle, whereas with progestin-only pills (which thin the endometrium) fertilization rates are from 33% to 65% per cycle.<sup>5</sup>

### **What Are the Side Effects of Hormonal Contraceptive Use?**

#### **Relationship to Cancer**

The National Cancer Institute states: “The risk of endometrial and ovarian cancers is reduced with the use of OCs [oral contraceptives] while the risk of breast and cervical cancer is increased.”<sup>3</sup> An increased risk of liver cancer is also associated with OC use. (6) According to the U.S. Centers for Disease Control and Prevention, from 2004-2008, 2.3 times as many women died from breast, cervical and liver cancer as died from endometrial and ovarian cancers.<sup>7</sup>

The International Agency for Research of Cancer of the World Health Organization states: “artificial contraceptives are carcinogenic on a par with cigarettes and asbestos.”<sup>6</sup>

In a review of 34 case-control studies from various countries of the relationship between prior OC use and premenopausal breast cancer, researchers concluded that “Use of OCs was associated with an increased risk of premenopausal breast cancer in general,” increasing the risk by 19%. The association was particularly strong for women who used OCs before a first full-term pregnancy, increasing their risk by 44%.<sup>8</sup>

A more recent study of 1,102 women aged 20 to 49 randomly selected from a large U.S. integrated health care delivery system, with matched controls, and who had been diagnosed with invasive breast cancer from 1990 to 2009, found that the dose of hormones in the pill had an effect on the likelihood of developing breast cancer. High dose estrogen pills increased breast cancer risk 2.7 fold, while moderate dose estrogen increased risk 1.6 fold.

Moreover, “pills containing ethynodiol diacetate” (e.g. Zovia and Demulen) “increased risk 2.6 fold, and triphasic combination pills” (e.g. Ortho-Tri-Cyclen, Tri-Levien, and Triphasi) “containing ... an average of .75 milligrams of norethindrone increased the risk 3.1 fold.”

Low dose estrogen pills were not found to increase the risk. Overall, the study found that recent use of oral contraceptives increased the risk of breast cancer by 50 percent when compared with those who have never used the pills or are no longer using them.<sup>9</sup>

Using data from Denmark's national administrative and health registries, Dr. David Gaist and colleagues identified all the women between 15 and 49 who had a first-time diagnosis of glioma, a relatively rare type of brain cancer. They found 317 cases and compared them to matched controls. Women who had used hormonal contraceptives increased their risk of this type of brain cancer by 50%, while those who had used birth control for over five years nearly doubled their risk.<sup>10</sup>

### **Relationship to Circulatory Disorders**

Nichols notes that "the Physician's Desk Reference (PDR) states that users of birth control are three times more likely to develop superficial venous thrombosis [blood clots], and have a four to eleven times greater risk for deep vein thrombosis or pulmonary embolism than non-users. The risk goes up by a factor of 1.5 to 6 for those women who are genetically predisposed to clots.<sup>11</sup> On top of this "well-established" risk, two recent studies indicated that hormonal contraceptives containing drospirenone (a type of progestin) increase the risk 2-3 times more. The U.S. Food and Drug Administration did its own study and found an increased risk of 1.5 times compared to hormonal contraceptives not containing drospirenone. A six year study of 329,995 women in Israel also found an increased risk of 1.43 to 1.65 times of deep vein clots over hormonal contraceptives not containing drospirenone.<sup>12</sup> Contraceptives containing this substance include Yaz, Gianvi, Loryna, Yasmin, Ocella, Syeda, Zarah, Beyaz and Safyral.<sup>13</sup> High blood pressure is also a fairly common effect of the use of hormonal contraceptives. The risk of strokes and heart attacks also increases. "Over 12,000 U.S. women have filed lawsuits against Bayer for blood clot related injuries while taking Yaz or Yasmin. The FDA has received as many as 50 reports of deaths linked to the drug."<sup>14</sup> Bayer's 2013 Annual Statement, released in February 2014, indicated it agreed to pay more than \$1.69 billion to settle some 8,250 lawsuits alleging women suffered from heart attacks, strokes, pulmonary embolisms, or deep vein thrombosis from either Yaz or Yasmin.<sup>15</sup> These birth control pills have been linked to the deaths of at least 23 Canadian women between 2007 and June, 2013.<sup>16</sup>

Besides the contraceptive pill, other contraceptive devices have been the subject of lawsuits by women suffering negative consequences as a result of their use. For example, some 105 lawsuits have been filed in federal courts, and some 170 in state courts regarding the IUD Mirena, also manufactured by Bayer Pharmaceuticals. Over 50,000 Adverse Event Reports have been filed with the FDA regarding this device. Alleged complications have included ectopic pregnancy, infertility, perforation or embedment of or in the uterine wall, cervix and pelvic organs, migration of the IUD, pelvic inflammatory disease and other serious infections.<sup>17</sup>

The injectable contraceptive Depo-Provera and its manufacturer Pfizer have been the object of million dollar lawsuits in the U.S. and Canada. Complications from its use include severe osteoporosis if used over two years, increased risks of breast cancer and AIDS.<sup>18</sup>

NuvaRing is a contraceptive device inserted into the vagina which releases hormones. Its side effects allegedly include heart attacks, blood clots, strokes and elevated breast cancer levels. Complaints filed with the FDA indicate 2,955 women have been hospitalized and 224 have died from its side effects. Merck Pharmaceuticals has agreed to pay some 4,000 plaintiffs a \$100 million settlement.<sup>19</sup>

The transdermal skin patch Ortho Evra, manufactured by Ortho-McNeil Pharmaceuticals, is suspected in at least 23 deaths. Over 16,000 Adverse Event Reports have been filed with the FDA. Strokes, heart attacks and blood clots in the legs and lungs are among its complications. Some \$68.7 million have been paid in out-of-court settlements by the manufacturer.<sup>20</sup>

### **Other Negative Effects on Health.**

A recent study published by the Centers for Disease Control and Prevention (CDC) noted that women who had previously been diagnosed with gestational diabetes (GD) and had used hormonal contraceptives had a higher

risk of developing type 2 diabetes. This study also found that women not previously diagnosed with GD who used hormonal contraceptives were 43% more likely to develop it than were those who did not use any birth control method.<sup>21</sup> GD is usually diagnosed in the 24<sup>th</sup> through 28<sup>th</sup> week of pregnancy. If uncontrolled, it can lead to overweight fetuses, which can result in caesarian sections, preeclampsia and low blood sugar in the mother, jaundice in the baby, and increased risk of type 2 diabetes in both mother and child later in life.

Two large studies indicate there is an association between the use of birth control pills and an increased risk of glaucoma – a leading cause of blindness. The first was a 2011 study involving almost 75,000 women over the age of 40. It found that women who used birth control pills for over five years had a 25% increased risk of having glaucoma.<sup>22</sup> A 2013 study of 3,406 women over 40 who participated in a national CDC survey found that women using oral contraceptives for more than three years were more than twice as likely to be diagnosed with glaucoma.<sup>23</sup> Exposure to estrogen in the pills was suspected to be the cause in both studies.

Some smaller studies suggest the use of hormonal contraceptives other than the pill also have negative impacts on women's health. For example, a study of 95 women over two years who used DMPA, the birth control shot (administered once every three months) indicated that 45 of them experienced high bone mineral density loss in the hip or lower spine. This was particularly true of those women who were current smokers, had never given birth, and had a low daily calcium intake. Twenty seven of these women followed for a third year continued to lose bone mass.<sup>24</sup>

Another study of 70 non-smoking minority women, 30 of whom used either OCs, the vaginal ring, or the transdermal patch had significantly lower levels of essential vitamins and antioxidants compared to 40 controls. The transdermal patch appeared to have the most negative effect. The vitamins and antioxidants involved are important to body cell health, and over the long term could be related to many chronic diseases, including cardiovascular disease, cancer, cataracts, and aging.<sup>25</sup>

## EMERGENCY CONTRACEPTIVES OR MORNING AFTER PILLS

**There are two main types** of “emergency contraceptives” or “morning after pills.”

1. The first type, introduced in 2006, contains Levonorgestrel and goes by the names of **Plan B**, **One-Step**, and **Next Choice**. These became available over-the-counter for women 17 and older, and for male partners 17 and older in 2009. If taken within 72 hours of intercourse, they work by interfering with implantation of the embryo, or, if conception has not occurred, by suppressing ovulation or inhibiting sperm migration. A study published in the journal *Fertility and Sterility* found that 10% of 7,300 sexually active women aged 15-44 reported ever using an emergency contraceptive.<sup>26</sup>
2. The second type, introduced in 2010, is called **ella**, and contains ulipristal acetate. It is available only by prescription, and is said to be effective up to five days after intercourse. Unlike Plan B and other emergency contraceptives noted above, ella works like mifepristone, a major component of the abortifacient RU 486. It blocks the body's progesterone, a hormone necessary to build and *maintain* the uterine wall. Hence, ella can cause the demise of an already-implanted human embryo as well as preventing implantation. In approving ella, the U.S. Food and Drug Administration said it may “affect” implantation. In contrast, when describing Plan B's action, it said that the drug may “prevent” implantation. It also explicitly stated that Plan B would not terminate an established pregnancy (i.e., one wherein the embryo had implanted). Hence, whether one considers pregnancy as commencing with fertilization or implantation, ella is an abortifacient.<sup>27</sup> It should also be noted that ella is contraindicated if the woman is pregnant and wants to maintain the pregnancy, or if she is breastfeeding.<sup>28</sup>

## NATURAL FAMILY PLANNING

For child-spacing methods which are drug-free, avoid the negative health risks described above, and require and enhance communication between husband and wife, go to any of these websites: [www.americanpregnancy.org](http://www.americanpregnancy.org), Couple to Couple League [www.ccli.org/nfp](http://www.ccli.org/nfp) or [www.NFPandmore.com](http://www.NFPandmore.com).

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