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# Women, Birth Control Pills, and Thrombophilia: An Analysis of Risk Communication

Kerry Gomer

Clemson University, [kerrygretchen@gmail.com](mailto:kerrygretchen@gmail.com)

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WOMEN, BIRTH CONTROL PILLS, AND THROMBOPHILIA:  
AN ANALYSIS OF CURRENT RISK COMMUNICATION

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A Thesis  
Presented to  
the Graduate School of  
Clemson University

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In Partial Fulfillment  
of the Requirements for the Degree  
Master of Arts  
Professional Communication

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by  
Kerry Gretchen Gomer  
May 2009

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Accepted by  
Dr. Sean Williams, Committee Chair  
Dr. Cynthia Haynes  
Dr. David Novak

## **ABSTRACT**

The Surgeon General recently issued a call to action to reduce the incidents of blood clots, which can cause pulmonary embolism, deep vein thrombosis, and stroke. This research study was conducted to assess what risk information is available to women regarding thrombosis (blood clots) and thrombophilia (clotting disorders) in combination with birth control pills, what women know about this issue, and how to increase this awareness. A media analysis showed that very little information is available to women about thrombosis and thrombophilia with regard to birth control pills. It also demonstrated that the information that is available is often inadequate or inaccurate.

The survey of women who have taken or are taking birth control pills showed a lack of awareness of the side effects of birth control pills, thrombophilia, thrombosis, or the symptoms of thrombosis. Most women taking this medication that increases their risk of blood clots are not even aware of the symptoms of blood clots. Additionally, only one woman out of 311 could correctly identify all of the health risks associated with birth control pills. The survey results also showed that the majority of women would not only be willing to take a blood test to determine if they have thrombophilia, but more than half would be willing to pay for it.

In order to reduce thrombosis, awareness of these conditions can be increased by pharmaceutical manufacturers taking a greater responsibility for producing easily understandable risk information. Also, health care providers and patients must communicate more effectively. At a minimum, testing should be offered to women, if not required, before prescribing birth control pills.

## **DEDICATION**

This thesis is dedicated to my husband, Joshua. Without you, this thesis would, quite literally, not have been possible. Thank you for all that you are and all that you do. And thank you for believing in the value of my work, even when I am full of doubts. At the risk of sounding uncharacteristically schmaltzy, I love you very much and am so grateful to be on this journey with you.

I would also like to thank my mother and my sister for their patience, support, and understanding- of a process that can be quite difficult to understand.

## **ACKNOWLEDGMENTS**

I would like to take this opportunity to thank all of the women who took my survey. I am so grateful for your quick response and especially for your candor. What you shared was invaluable to this research.

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## **PREFACE**

*The educated differ from the uneducated as much  
as the living from the dead.*

-Aristotle

### **MY STORY**

I opened my eyes and saw my husband, Josh, leaning over me. I was on my side in the emergency room and the doctor had just asked Josh to hold me steady while he gave me a spinal tap to check for meningitis. Josh held me so firmly, understanding the consequences of a misplaced needle, that his arms were shaking from the strain. The doctor attempted a lighthearted joke about me getting an epidural in the future and Josh laughed nervously. I wanted to tell him, “Don’t worry about holding me steady. I can’t move anyway.” I had lost the use of my limbs hours before, maybe even days. And now it seemed my power of speech was gone, as well.

It was not the first time Josh had to hold me down. Earlier that day, he had tried to restrain me while my body thrashed wildly, nearly bucking him off the couch. During the seizure, I told myself that if I just calmed down, it would stop. It must be all in my head, since I had already been sent home from the emergency room twice in as many days. When the shaking finally subsided, we locked eyes, both of us terrified of what was happening to me. Josh asked me if he should call 911 again. All I could do was nod.

I did not have meningitis. I had a common blood condition that predisposed me to getting blood clots. And when combined with the estrogen in my birth control pills- pills that I had been taking for ten years- this common condition was nearly fatal. The blood clots were in my brain, and because they had not been treated right away, one of the veins in my head had burst and was bleeding into my brain.

## **CHAPTER ONE**

### **INTRODUCTION**

On September 15, 2008, the Office of the Surgeon General issued a *Call to Action* to reduce the number of cases of venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE), in the United States. Together, these conditions affect an estimated 350,000 to 600,000 Americans each year, causing at least 100,000 fatalities. Acting Surgeon General Steven K. Galson, M.D., M.P.H. said, “It’s a silent killer. It’s hard to diagnose. I don’t think most people understand that this is a serious medical problem or what can be done to prevent it.” He urged all Americans to learn about and prevent these treatable conditions.

“It is well established that thrombosis is a complex disease with a very high genetic component (i.e., heritability of 61%) that determines the risk of disease” (Lopez et al. 349). Researchers have found that VTEs develop most frequently in people who have both genetic risk factors and circumstantial increased risk factors. Circumstantial factors that increase the risk of thrombosis include age, inactivity, surgery, pregnancy, oral contraceptives, hormone replacement therapy, and obesity. Genetic risk factors include inherited thrombophilias. “Thrombophilia may... be defined as both an acquired or congenital abnormality of haemostasis predisposing to thrombosis” (Middeldrop 1). Or, in more common terms, thrombophilia is a blood condition that increases the likelihood of blood clots.

## **FACTOR V LEIDEN**

“In the 1990’s, several gene mutations were found to substantially increase the risk of thrombosis” (Mohllajee 166). One of these is factor V Leiden (FVL), a 20,000-year-old mutation common in the general population and a major genetic risk factor for thrombosis (Dahlback 19). The prevalence of factor V Leiden varies among different ethnicities and is highest in Caucasians but significantly lower in other groups (Eckman et al. 109). This genetic mutation is found in approximately 3-7% of the Caucasian population (Walker 8). Factor V Leiden can present in patients as either heterozygous, when the patient has inherited one mutated gene from a parent, or homozygous, where the patient has inherited two mutated genes, one from each parent (Crawford 26).

“The factor V Leiden mutation appears to increase the risk of VTE approximately 7-10 fold and in Caucasians is at least 10 times more prevalent than any of the natural anticoagulant deficiencies” (Walker 9). It is the most common genetic cause of primary and recurrent venous thromboembolism in women (Ament 51).

One circumstantial factor that can increase the risk of blood clots, stroke, and heart attack in women is taking estrogen. When someone with FVL takes estrogen, her risk of blood clots increases exponentially. Whether women are taking estrogen in the form of oral contraceptives, have increased levels of estrogen due to pregnancy, or are on hormone replacement therapy, they are at much greater risk of clotting. Lidegaard, et al. found that the “risk [of VTE] increased more than 100% with increasing estrogen dose” (187). Mohllajee et al. found 10 studies that provided evidence of a greater risk of VTE among oral contraceptive users with FVL. According to Dahlback in his review of blood coagulation and genetic factors in *Blood*, the journal for the American Society of

Hematology, women with heterozygous FVL who also use oral contraceptives have an estimated 30 to 50-fold increased risk of blood clots, while women with homozygous FVL have a several hundred-fold increased risk (24).

Additionally, FVL accounts for 20-50% of the venous thrombosis events that are pregnancy related (Ament 51). And in the United States, VTE is the leading cause of maternal death (Dresang 1709). In addition to causing VTE in pregnant women, FVL has been linked to miscarriage, preeclampsia, placental abruption, and stillbirth. “In a recent review, 25 studies were evaluated investigating the association between thrombophilia and early pregnancy loss (first and second trimester) and 15 studies were analyzed to define the association between thrombophilia and late pregnancy loss (third trimester). Significant associations with early and late pregnancy loss were observed for carriers of heterozygous factor V Leiden mutation... associations in late pregnancy loss are even stronger than in first trimester miscarriages” (Lindhoff-Last 24).

Perhaps the women most at risk for blood clots are those that have been placed on hormone replacement therapy (HRT). A recent review of data from eight observational studies and nine randomized controlled trials found that women taking the oral form of the drug were two to three times more likely to develop a blood clot (Oral HRT increases risk of blood clots 7). And women with factor V Leiden who are also on HRT were 14-16 times more likely to have a VTE (Park 463).

Despite these risks, women are not systematically tested for FVL before they are prescribed oral contraceptives, before or during pregnancy, or before commencing HRT. This is due to a series of outdated cost-effectiveness studies that found the benefits, measured in cost per prevention of one death, do not outweigh the cost of testing.

Regardless of the cost of the tests, women are not even informed about these inherited and dangerous conditions.

## **COMMUNICATION**

The problem with not informing women of the dangers of clotting disorders when taking birth control pills becomes even more apparent when the number of women taking them is considered. According to the National Center for Health Statistics, it is estimated that 11.8 million women in the United States, and 80 to 90 million worldwide, use oral contraception. And recent studies have suggested that 80% of women around the world use oral contraceptives at some point between the ages of 18 and 24 (Berry, et al. 305). As Berry, et al. point out, “Given the widespread usage, one might expect people to have a good understanding of the risks involved” with taking oral contraceptives, “however, recent research has shown that even relatively well educated women were woefully uneducated about the side effects” (305).

Bryden concurs adding that “there are many misconceptions about both the health-related benefits and health-related risks of [oral contraceptive] use” and that younger women appear to be even less knowledgeable (223). In their 2001 study, Fletcher, et al. found that procedures surrounding the prescription of oral contraceptives are inconsistent among health care professionals (231). Their study also indicated that women lack adequate knowledge about pill use (233).

A study done by Tatum et al. in Mexico City found that “both public and private physicians asked few questions and provided little information regarding screening, pill-taking instructions, side effect information and warning sign information” (208).

Unfortunately no similar studies could be found for physicians in the United States, though the findings presented in this thesis are comparable.

In 2002, the Berry et al. study tested the effectiveness of the warning information provided to women taking the pill. They found “that less than 12% of educated women fully understood the absolute levels of risk of thrombosis from taking the pill” and that “understanding of relative risk was also poor, with less than 40% showing a full understanding and 20% no understanding” (Berry 306). And “recent research has shown that even highly educated people have difficulty comprehending abstract quantitative information, such as statistics about the chance of experiencing complications from treatment” (Zikmund-Fisher 113).

Additionally, a recent study by Gigerenzer et al. has shown “that information pamphlets, Web sites, leaflets distributed to doctors by the pharmaceutical industry, and even medical journals often report evidence in nontransparent forms that suggest big benefits of featured interventions and small harms” (53). According to their research, the majority of the sources that doctors use for information are incomprehensible to them, or worse, give them a false understanding of treatment benefits and risks.

If women and even their doctors do not understand the risks associated with birth control pills, it is unlikely that they will further have knowledge of clotting disorders and how they increase these risks. To this, a study by Hellman et al. of patients with FVL found that “fewer than half the individuals (47%) felt comfortable with their healthcare providers’ understanding of FV Leiden.” They also found that 42% of the patients surveyed tried to research FVL independently without much success. The study indicates that there is a lack of available information about FVL. (2335-2338).

Indeed, it would be highly unusual for a woman to come across information about factor V Leiden or any other, less common clotting disorder. If one were to search the term “factor V Leiden” in any of the major search engines (Google, Yahoo, AOL, MSN- searched on March 23, 2009) the main site that is found is [www.fvleiden.org](http://www.fvleiden.org). This site describes itself as the “Thrombophilia Awareness Project” and “the web’s resource for patient based thrombophilia information.” It was created in 1998 by Debra Okner Smith, a woman with factor V Leiden who wanted to provide a resource for other people with the clotting disorders. Smith has since obtained the input of Dr. Stephen Moll, director of the Thrombophilia Program at the University of North Carolina, Chapel Hill to answer questions on one page of the website. Regardless of the modest input by Dr. Moll, the main online resource for factor V Leiden was started and is maintained by a woman with no medical background, aside from her own personal history of clotting disorders (including a DVT while she was on oral contraceptives).

The National Alliance for Thrombosis and Thrombophilia (NATT) maintains the website [www.stoptheclot.org](http://www.stoptheclot.org), an excellent resource for information on blood clots and clotting disorders. However, this site does not appear on the first page of any of the previously mentioned search engines for any of the following keywords: factor V Leiden, blood clots, clotting disorders, or thrombophilia. How can a resource help if it cannot be located?

For as common as factor V Leiden is in the general population, it receives very little attention, especially in the United States. To better understand the level that factor V Leiden is discussed, I signed up for a Google alert, an email from Google each week containing all new online listings of a chosen search term. For six months, I was emailed



any Internet activity that Google found with the term “factor V Leiden.” Fewer than a dozen news stories were located, with most of those originating in India. The majority of the links included in the Google alerts were to blogs kept by women who were having fertility issues. Many of these women had miscarried two or three times or suffered stillbirths before being tested and found positive for factor V Leiden. One blogger shares (Radical Catholic Mom):

*Factor V Leiden is one of the things I \*SHOULD\* have been tested for when I lost our first second trimester baby and I had to fight to get tested for for[sic] our second, second trimester loss. It is a simple blood test. I have no clue why they won't test for it.*

If the warning information that comes with birth control pills does not adequately inform, even educated women; and if information on blood clots and clotting disorders is difficult to find; and if many doctors do not even inform patients of the risks of taking birth control pills or thrombophilia; what information *is* available to women about blood clots and thrombophilia, what do they *actually* know, and how can this knowledge be increased? This research attempts to answer these questions by analyzing information that is available to women and what information may be lacking. Women who have taken birth control pills were then surveyed to assess what information they already know and determine any deficiencies in their understanding. Finally, results of the first two parts of the study were combined with research to establish methods for increasing awareness.

## CHAPTER TWO

### METHODS

The aim of this study is to assess the understanding women have about blood clots and clotting disorders, and offer methods of increasing this awareness. Though all women with increased estrogen levels, whether through pregnancy, oral contraceptive use, or hormone replacement therapy, are at a higher risk of blood clots; for the purposes of this study, I focused primarily on awareness in women who have taken or are taking oral contraception. If 80% of women use oral contraceptives as young adults, increasing awareness when they are given the prescription could help prevent clots not only during the use of the medication, but also in future risk situations. Awareness in younger women could mean fewer clots in women during pregnancy and menopause, when hormone replacement therapy is generally prescribed. And possibly fewer blood clots caused by long flights, surgeries, and other circumstantial situations.

To determine how best to increase awareness of thrombophilia and the symptoms of blood clots, I first had to research what information is currently available to women and what women actually know about the subject. Therefore this study has three parts:

- I. What information is available about the health risks, symptoms of blood clots, and clotting disorders with regards to oral contraceptives?*
- II. What do women understand about the health risks, symptoms of blood clots, and clotting disorders with regard to oral contraceptives?*
- III. How can women's understanding of health risks, symptoms of blood clots, and clotting disorders be improved?*

To address my first question, I reviewed what information was available to women by analyzing three samples from each of three types of informative media. These samples were print advertisements for birth control pills, websites with medical

information, and inserts from pharmaceutical companies that are included in birth control pill packaging. Each media was chosen for the specific reasons outlined below.

Advertisements were the first medium chosen for analysis. Being exposed to advertisements is a passive process and analyzing print advertisements allowed me to review what kind of information women are exposed to when they are not seeking out information about birth control pills. Since 1997, when the FDA modified their regulations regarding pharmaceutical advertising, manufacturers have greatly increased their efforts to market direct to consumers and have increased their spending on advertising from \$40 million in 1997 to \$4.4 billion in 2004, an increase of over 10,000 percent (Choi 137). According to a survey conducted by the Food and Drug Administration (FDA) in 2002, 81% of participants reported that in the past three months they had seen or heard a prescription drug advertisement. That same year, 92% of physicians surveyed reported that they had patient-initiated discussions about advertised drugs. (Kaphingst 516).

Print advertisements were chosen over advertisements in other media because they contain more risk information. This is partly due to space and partly due to a provision by the FDA allowing drug companies that are advertising on television to refer consumers to concurrent print advertisements for additional information about drug risk and side effects (Kaphingst et al. 516). And in 2006, the FDA found the most common violation in pharmaceutical advertising was inadequate risk information.

The second medium analyzed was websites. Compared to print advertisements, web usage is a much more active process of obtaining information and is continually expanding in users and in information. A 2006 summary of the Pew Internet and

American Life Project showed that 79% of those surveyed had searched for health information online, which translates to approximately 95 million Americans. Furthermore, those most likely to search for health information online were women younger than 65. (Rice 9-10). In a 2007 study, Warner and Procaccino found that women who use the Internet are most active at seeking health information (801).

The three websites selected were health sites containing information about birth control pills. These sites were selected by inputting the keyword “birth control pills” into four search engines, with the results cross-referenced for the most popular results. Coincidentally, all three sites were maintained by not-for-profit organizations.

The third medium examined in this study was the inserts created by pharmaceutical companies that are included with packets of birth control pills. These inserts could be considered active or passive types of information depending upon how each consumer utilizes them: passive because a woman has simply to obtain birth control pills to receive the information; active because women would have to actually read through a great deal of dense material printed in very small font in order to glean any of the information provided.

Additionally, the pharmaceutical inserts are technical documents and were analyzed accordingly. One of the central tenets of technical communication is to consider your audience and design accordingly. As Schriver points out in *Dynamics in Document Design*, “Since people rely on documents to make decisions that influence their safety, livelihood, health, and education, the highest ethical standards must be brought to bear in making textual choices- in deciding what to say and what not to say” (11). Therefore,

what pharmaceutical inserts include *and* exclude, is of the utmost importance; as is how that information is presented.

Each item was reviewed for content and information about risk and side effects. Specifically, each item was examined for information to answer the following:

- Did the information state that thromboembolism is a health risk?
- If so, did the information state that genetic disorders can increase the risk of thromboembolism?
- Did the information list symptoms of a thromboembolic event?
- Did the information tell women with symptoms of thrombotic event what to do in that situation (i.e. got to the emergency room, etc.)?

In addition to these questions, the media were given a general overview with respect to how content and design conveys information. The choice of language was also analyzed, as wording plays an important role in our understanding of risk and benefit. As Davis has found, “the presence of qualifying language actually increases consumers’ positive perceptions of the drug and reduces the estimates of how likely they would be to encounter specific side effects” (620). Qualifying language often includes conditional words like ‘*may*’ and ‘*could.*’ For example, research has shown that phrases like ‘*some side effects may occur*’ or ‘*this medicine could cause certain side effects*’ have a “profound effect on the likelihood [of a patient to] request a drug and the anticipated positive experience of using a drug” (Davis 619).

To address the second part of my research question, I surveyed women who have taken or are taking oral contraception. The survey was created using SurveyMonkey.com and contained a variety of question types including multiple choice, fill in the blank, and open-ended comments. The survey was completely anonymous with the only

requirements that the participant had to be over 18 years of age and have taken birth control pills. The link to the online survey was emailed to friends and colleagues with the request that they forward it to any woman that met the criteria and would be willing to participate. Additionally, the link to the survey was posted on the social networking website Facebook.com.

Women were first questioned about their experience with birth control pills including interactions with both their healthcare provider and pharmacist. Then, the participants were asked about their knowledge of the risks involved with taking birth control pills, their behavior concerning prescription warning information, and where they are most likely to seek medical information. Finally, they were asked about thrombophilia, symptoms of blood clots, and whether they would be willing to take a blood test to assess their risk of blood clots.

The survey remained active online for 10 days during which time more than 300 responses were collected. After which the survey was deactivated and the results were collected from SurveyMonkey.com. The survey responses were then reviewed and analyzed. Questions that had “Other (please explain)” as an option were coded to see if the responses could be categorized into one of the other selections. After coding, the results were modified to reflect the updated responses.

The research collected through the media analysis and the survey was then reviewed to determine what information is lacking and how that information can be better communicated. These suggestions were researched and compiled in Chapter Five.

## **CHAPTER THREE**

### **MEDIA ANALYSIS**

To understand how risks are communicated to women with respect to thromboembolisms and birth control pills, this study analyzed magazine advertisements, websites, and the actual materials from pharmaceutical companies that accompany the OCs. For each medium, the information was examined for the following criteria:

- Did the information state that thromboembolism is a health risk?
- If so, did the information state that genetic disorders can increase the risk of thromboembolism?
- Did the information list symptoms of a thromboembolic event?
- Did the information tell women with symptoms of thrombotic event what to do in that situation (i.e. got to the emergency room, etc.)?

In addition to these questions, each item was reviewed for design and word choice. The choice of language was also analyzed for how it affected the risk communication, especially with regards to qualifying language.

#### **ADVERTISEMENTS**

Advertisements for birth control pills can be a major factor in sales, as evidenced by Yaz, which saw an increase in sales from \$262 million in 2007 to \$616 million in 2008, after an extensive advertisement campaign (Singer). Clearly advertising, at least for birth control pills, remains an effective means of marketing and persuasion. For this study, three print advertisements for birth control pills were selected for examination, two from popular women's magazines and a third that was distributed at a student health center on a university campus.

## *Yaz*

The first advertisement was for Yaz, the self-proclaimed “#1 brand birth control pill” and according to the New York Times, the best-selling oral contraception pill in the United States. The advertisement was taken from the December 2008 issue of *Shape* magazine, a popular women’s magazine with a fitness focus. This advertisement is comprised of three magazine pages (back of one page, and front and back of a second page). The date at the bottom of the last page of the advertisement is October 2007.

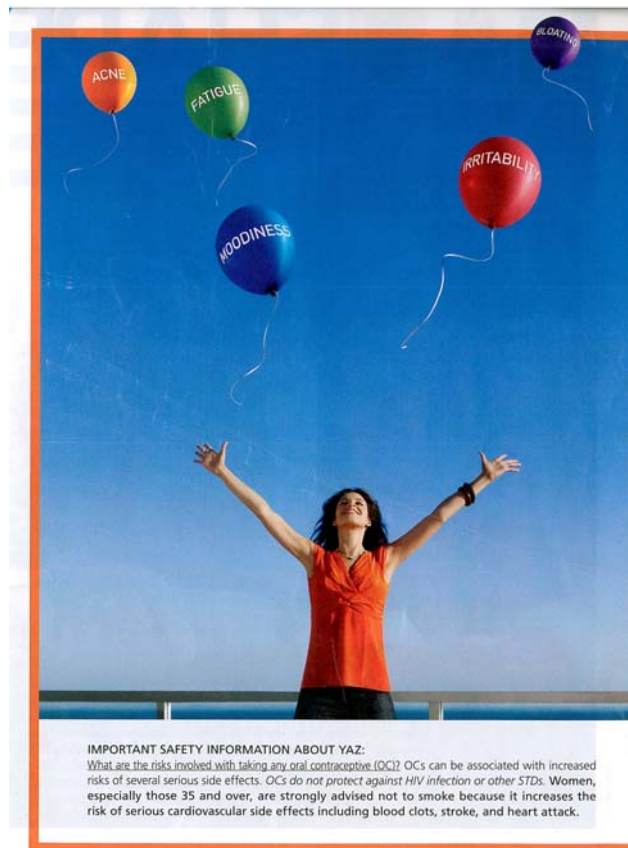


FIGURE 3.1: PAGE 1 OF YAZ ADVERTISEMENT



The top three quarters of the first page of the Yaz ad (Figure 3.1) is a picture of a smiling woman with her arms in the air. Balloons with terms like “acne” and “irritability” float high above her head. The visual rhetoric of the advertisement indicates that the woman is no longer tethered to “acne” and “irritability” and therefore carefree and happy. Under the carefree woman, at the bottom of the page is “Important Safety Information About Yaz.” Below that is the following, with the text manipulated by formatting each line differently, as it is in the advertisement:

What are the risks involved with taking any oral contraceptive (OC)? OCs can be associated with increased risk of several serious side effects. *OCs do not protect against HIV infections or other STDs.* **Women, especially those 35 and over, are strongly advised not to smoke because it increases the risk of serious cardiovascular side effects including blood clots, stroke, and heart attack.**

The formatting of this section is as interesting as the word choice. The designers of the advertisement emphasize that the serious side effects are a risk involved with taking any oral contraception. While this is true, the wording demonstrates a reluctance on the part of Yaz to take responsibility for these particular side effects. The ad also uses the conditional phrase ‘can be,’ instead of stating that “OCs *are* associated with increased risk of several serious side effects.” Both statements are true, but only one increases a consumer’s confidence in a medication.

Additionally, after the warning points out that birth control pills “can be” associated with serious side effects,” they fail to list any of those side effects. Instead, the warning shifts the reader’s attention to an entirely separate issue, pointing out how OC’s do not protect against STDs and highlight that information using italics. Though this

information is true as well, STDs are not a side effect of birth control pills, they are a side effect of unprotected sex.

Following the non sequitur regarding STDs, the warning returns to a “serious side effect” of OCs, cardiovascular issues. Here Yaz continues to diminish its culpability in these risks by emphasizing that the risk of cardiovascular side effects is something that only applies to women who smoke, “especially those 35 and over.” Many women interpret this phrase in the very manner that the advertisers want them to- that women are not at risk unless they smoke and are older. Unfortunately, all women who take birth control pills are at risk for cardiovascular side effects, including blood clots, heart attack, and stroke. And women who also have an inherited thrombophilia are at a much higher risk- in many cases, without even knowing it.

The second page (Figure 3.2) makes the claim that Yaz can treat premenstrual symptoms including the ability to “help keep your skin clear.” According to the advertisement, this has been demonstrated in non-specified recent studies where “9 out of 10 women saw improvement in their moderate acne.” This page also discusses the risk of increased potassium that is a side effect unique to Yaz. So, in addition to the side effects related to regular hormonal birth control pills Yaz, despite its popularity, carries additional risk factors. Why would a woman choose a birth control pill with more side effects over one with fewer? Perhaps because the claims of benefits are overstated while the risk information is understated.

**YAZ HELPS YOU SAY GOODBYE.**

YAZ, like all birth control pills, is 99% effective, but it's the first and only birth control proven to treat the emotional and physical premenstrual symptoms severe enough to impact your life, a condition doctors call PMDD.

Symptoms could include:

- Irritability
- Moodiness
- Feeling anxious
- Bloating
- Increased appetite
- Fatigue
- Headaches
- Muscle aches

YAZ can also help keep your skin clear. In recent studies, 9 out of 10 women saw improvement in their moderate acne.

YAZ is for women who choose the Pill for contraception. It should be taken as directed, and is available by prescription only.

**Who shouldn't take YAZ?**  
 YAZ contains a different kind of hormone that may increase potassium. Therefore, you should not take YAZ if you have kidney, liver, or adrenal disease because this could cause serious heart and health problems. Tell your doctor if you are on daily long-term treatment for a chronic condition such as cardiovascular disease or chronic inflammatory disease. Women who take certain drugs (see below) should have their potassium levels checked in the first month of taking YAZ.

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.**

Only YAZ goes beyond birth control. Talk to your healthcare professional today to find out if YAZ can help you say goodbye.

**YAZ** (drospirenone & ethinyl estradiol)  
**BEYOND BIRTH CONTROL™**  
 The #1 brand birth control pill\*

[www.YAZ-us.com](http://www.YAZ-us.com) **1-866-YAZ-PILL**  
\*among OBGYNs and Dermatologists

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What cardiovascular or chronic inflammatory drugs may increase potassium? NSAIDs—ibuprofen (Motrin®, Advil®), naproxen (Naprosyn®, Aleve®, and others) when taken long-term and daily for arthritis or other diseases or conditions, Potassium-sparing diuretics (spironolactone and others), Potassium supplementation, ACE inhibitors (Capoten®, Vasotec®, Zestril®, and others), Angiotensin-II receptor antagonists (Cozaar®, Diovan®, Avapro®, and others), Heparin, and Aldosterone antagonists. See important patient information on reverse side.

FIGURE 3.2: PAGE 2 OF YAZ ADVERTISEMENT

The final page is a “Brief Summary Patient Package Insert.” (see Appendix A). The page consists of three columns of text in an extremely small, almost unreadable font. Approximately two thirds of the way down the first column, the advertisement states that women “should understand the benefits and risks of using the Pill” and that the information they provide “is not a replacement for a careful discussion” with a healthcare professional.

On this page, Yaz does list blood clots as a risk and mentions that clotting disorders increase those risks. This information is in the same tiny font as the majority of

the page. Under that information, in a separate box and in bold font, is a similar disclaimer to the one found on the front page regarding increased risks of women who smoke. While it is true that the risk of blood clots for women who smoke and/or are over 35 is increased, the risk for women with clotting disorders is also greatly increased yet this information is not highlighted. Moreover, women who are over 35 and/or smoke are aware that they are over 35 and/or smoke, while most women with inherited thrombophilia are not usually aware they possess this mutation.

Though clotting disorders are listed as an increased risk factor, the symptoms of blood clots are not addressed. Further down, the advertisement does state that information about symptoms is included with the prescription. It also states that women should “notify your healthcare provider if you notice any unusual physical disturbances while taking the pill.” This recommendation is buried in the middle of the page in barely readable font, likely to downplay the seriousness of the side effects. If they were to print in bold boxed letters to contact a doctor immediately at the onset of symptoms, it may make the medication appear more dangerous. And the statement is too broad to be of any use to most women, especially a woman who experiences major symptoms during an evening, weekend, holiday, or any other time her health care provider cannot be reached.

Overall, the Yaz advertisement avoids taking responsibility for cardiovascular side effects by using conditional language and inculcating all other oral contraceptives. Also, the advertisement intentionally shifts the focus away from serious side effects by placing a disclaimer about STDs in the middle of the warning. It mentions clotting disorders but provides no indication that women could have a clotting disorder and be unaware of it. Additionally, the advertisement fails to list the symptoms of a cardiovascular event, and

does not provide women with adequate guidance should they experience serious side effects. Perhaps the most disturbing inadequacy is the advertisement's misleading implication that clots are only a risk to those over 35.

It should be noted that during the course of this study, the Food and Drug Administration has required Bayer to run advertisements to correct previous Yaz marketing. "Regulators say the ads overstated the drug's ability to improve women's moods and clear up acne, while playing down its potential health risks" (Singer). Television commercials for Yaz have already been amended and updated print advertisements are scheduled to appear in forthcoming national magazines. According to *The New York Times*, in addition to the \$20 million corrected advertisement campaign, Bayer has agreed to submit all Yaz ads for federal review for the next six years. The previously mentioned sales increase of Yaz in the United States from \$262 million to \$616 million occurred during the misleading advertising campaign (Singer).

### ***Lybrel***

The second advertisement is for Lybrel, a birth control that proclaims that it "makes it possible to go without your monthly period." This advertisement was taken from the March 2008 issue of *Cosmopolitan* magazine, the best-selling magazine for young women (ages 18-34), according to [www.cosmomediakit.com](http://www.cosmomediakit.com). This advertisement is one page with print on the front and back. The bottom of the back page lists a revision date of May 2007.

**Take a look at LYBREL.**  
**Birth control that makes it possible to go without your monthly period.**

**What is the LYBREL difference?**  
 LYBREL is the first and only FDA-approved low dose combination birth control pill that you take every day, 365 days a year without placebos. This means it's possible to go without your monthly period for as long as you take LYBREL. While women stop having their regular monthly periods, most women initially experience breakthrough bleeding and spotting. This usually lessens over time. For some, this may continue, but regardless of any unexpected bleeding, LYBREL remains highly effective birth control.

**Is it OK to not have my period?**  
 Many health care professionals agree that there is no need to have a period while taking the Pill. Just ask yours.

**How do I learn more about LYBREL?**  
 Ask your health care professional. You can also visit [www.lybrel.com](http://www.lybrel.com) or call 1-877-LYBREL-0.

**IMPORTANT SAFETY INFORMATION**  
**The Pill does not protect against HIV or other sexually transmitted diseases.**  
 Some women should not use the Pill, including women who have blood clots, breast, uterine, or liver cancers; a history of heart attack, stroke, or breast cancer; and those who are or may be pregnant. Serious risks associated with the Pill which can be life threatening, include blood clots, stroke, and heart attacks.  
 Cigarette smoking increases the risk of serious adverse effects on the heart and blood vessels from oral contraceptive use, especially if you are over 35. Women who use the Pill are strongly advised not to smoke.  
 LYBREL provides more hormonal exposure per year than conventional cyclic oral contraceptives containing the same or similar strength of the hormones estrogen and progestin. Because regular monthly bleeding does not occur on LYBREL, it may be difficult to recognize if you get pregnant. If you suspect pregnancy, or if you have symptoms such as nausea/vomiting or unusual breast tenderness, you should take a pregnancy test and contact your health care professional.  
 The most common side effects reported with LYBREL in a clinical trial were headaches, menstrual cramps, upper respiratory infection, vaginal bleeding, and nausea.

**Lybrel**  
 (30 mcg levonorgestrel/20 mcg ethinyl estradiol)  
 TABLETS  
 learn more at [www.lybrel.com](http://www.lybrel.com)

LYBREL and LYBREL with skin are registered trademarks of Wyeth.  
 Wyeth © 2007. Wyeth Pharmaceuticals Inc., Philadelphia, PA 19101  
 214781-01

Please see Brief Summary of Patient Information on the adjacent page.



FIGURE 3.3: PAGE1 OF LYBREL ADVERTISEMENT

On the first page of the advertisement (Figure 3.3), toward the bottom left part of the page, there is a barefoot woman standing with arms outstretched behind her as the wind appears to blow back her skirt and fabric she is holding. Her head is tilted upward toward the sky and she is smiling. The visual rhetoric of this image suggests that the woman is happy and free. The title reads “Take a look at Lybrel” with the subtitle “Birth control that makes it possible to go without your monthly period.” Presumably this is why the woman in the image is so happy.

The textual information for this advertisement is presented in question/ answer format. This gives the impression that Lybrel is open to addressing any concerns about their product. The format also allows Lybrel to play two roles in the advertisement- the role of the questioner and the role of the answerer. By presenting information this way, it conveniently entitles them to provide the information they choose with the appearance of two entities participating in the exchange. The format encourages women to put themselves in the role of the questioner, leaving an imagined expert in the role of the answer provider. By carefully masking that both roles are a creation of Lybrel, the advertisement creates the sense of a conversation with a trusted professional, as opposed to a sales pitch.

The first question, “What is the Lybrel difference?” describes how Lybrel is the “first and only” FDA-approved birth control pill that you can take all year and not menstruate. Under this, the advertiser uses qualifying language to discuss the side effect of breakthrough bleeding. Here, the advertisement uses conditional language and then couches it with a disclaimer: “for *some*, this [breakthrough bleeding] *may* continue, but regardless... Lybrel remains highly effective birth control.” This sentence indicates that women should dismiss bleeding because Lybrel still works despite that side effect. Never mind that the very marketing for this pill is based on women taking it to avoid being inconvenienced by a period.

The second question asks “Is it OK to not have my period?” According to the advertisement, “many health care professionals agree” that it is fine to not have a period while using OC. Nowhere does it state how many or which health care professionals, but it does suggest “Just ask yours.” Here the invisible expert is telling women “oh, everyone

says it is fine, if you don't believe me, just ask your doctor." This is followed by the prompt "How do I learn more about LYBREL?" that encourages women to seek out this medication.

On the left side of the advertisement is a column of text titled "Important Safety Information" bolded and in all capital letters. Under that, also in bold is the disclaimer that the pill does not protect against STDs. Then below that in standard font:

*Some women should not use the Pill, including women who have blood clots; breast, uterine, or liver cancers; a history of heart attack, stroke, or breast cancer; and those who are or may be pregnant. Serious risks associated with the Pill which can be life threatening, include blood clots, stroke, and heart attacks.*

By stating that women "who have blood clots" should not use the Pill, this warning suggests that as long as a woman does not currently have a clot, she can use this medication. Also in this section, more conditional language is used: "which can be life threatening." Though this study cannot state with absolute certainty, after considerable research and personal experience, this researcher has found that all blood clots, especially those causing strokes and heart attacks, are *actually* life threatening.

Following that disclaimer, and underlined, is the warning that cigarette smoking increases the risk, especially in women over 35. Here the warning is worded as "serious adverse effects on the heart and blood vessels." By using this phrasing in the warning, they have effectively decreased the understanding that smoking and age increase the risk of blood clots, heart attack, and stroke. While it may be clear to some that "adverse effects on the heart and blood vessels" are blood clots, heart attack, and stroke, many women may not make that connection.



At the bottom of the front page, the advertisement asks women to “Please see Brief Summary of Patient Information on the adjacent page.” This information is printed on the back of the advertisement in smaller but readable font (see Appendix A). At the top of this page in bold is another warning about birth control pills not protecting against sexually transmitted diseases. About one third of the way down the page is the warning that although most women can take oral contraceptives safely, “there are some women who are at high risk of developing certain serious diseases that can be life-threatening or may cause temporary or permanent disability or death.” Once again, the risk information is presented using conditional language: “some women,” “certain diseases,” “can be life-threatening,” and “may cause temporary.”

This section then lists with bullet points the risk factors for serious side effects including “have high blood pressure, diabetes, high cholesterol, or a tendency to form blood clots, or are obese” and “have or had clotting disorders, heart attack, stroke, etc.” In addition, “have headaches with neurological symptoms” is listed as a high risk factor. This is relatively new medical information that is further discussed in the next section of this manuscript.

Additionally, there is a box that is bolded with text explaining the increased risk for smokers, especially those over 35 years of age. Under that, it lists the serious side effects of the pill that “occur very infrequently, especially if you are in good health and do not smoke.” The advertisement does not list any of the symptoms of these side effects. But, it does recommend that women notify their healthcare provider if they notice “any unusual physical disturbances.”

The Lybrel advertisement does list blood clots as a side effect of taking birth control pills, though on the front page where it warns against smoking, it describes the side effects more vaguely as “serious adverse side effects on the heart and blood vessels.” On the back page, the advertisement does warn that their product is not for women who have tendencies to form blood clots or “have or have had clotting disorders.” Unfortunately, there is no indication that a woman may not know she has a clotting disorder as well as no symptoms of the serious side effects listed. Additionally, the weak recommendation that women should notify their health care provider should they notice any “unusual disturbances” undermines the seriousness of these side effects.

### ***Loestrin 24 Fe***

The third advertisement is for Loestrin 24 Fe and was collected from a student health center at a major university. The Loestrin 24 Fe flyer has the same dimensions as the other advertisements. It was distributed to the college, and is dated March 2008. This advertisement is one page, front and back, with the majority of the patient information on the back. It should be noted that though the front of the advertisement is dated March 2008, the information on the back states “Revised November 2006.”

The front page of this advertisement (Figure 3.4), on the left side of the page, shows a young woman, dressed like a college student in a t-shirt and jeans, her head tilted, looking at the camera. She appears confident and relaxed, like she might be getting ready to have a conversation with a friend. Her stomach is just slightly exposed, not enough to be considered tawdry, just enough to indicate the independence expressed in the tag line “Your pill. Your choice.”

**What Pill Are You On?**

► **Does your birth control pill contain a recommendation for a blood test?**

- If you take birth control pills that contain drospirenone, such as Yaz® (drospirenone and ethinyl estradiol) or Yasmin® (drospirenone and ethinyl estradiol tablets), your doctor may ask you to get a blood test to check your potassium level. Some common medications taken on a daily, long-term basis, may raise your potassium level, especially when taken with Yaz® or Yasmin®. Always tell your doctor when you start taking other medications while you are on a birth control pill.

With Loestrin® 24 Fe you don't have to worry about a blood test\* and you get short periods that last, on average, 3 days or less!†  
Ask your doctor about Loestrin® 24 Fe today.

**Loestrin<sup>24</sup> Fe**  
(norethindrone acetate and ethinyl estradiol tablets, USP and ferrous fumarate tablets)

Your pill. Your choice.

\*The FDA-approved prescribing information for Loestrin® 24 Fe does not reference the need for a blood test.  
†In a clinical trial, on average, women taking Loestrin® 24 Fe had a period that lasted less than 3 days by cycle 6.

**Important Safety Information about Loestrin® 24 Fe:**  
Oral contraceptives are not for everybody. Most side effects of the Pill are not serious and those that are, occur infrequently. Serious risks, which can be life threatening, include blood clots, stroke, and heart attacks, and are increased if you smoke cigarettes. Cigarette smoking increases the risk of serious cardiovascular side effects, especially if you're over 35. Women who use oral contraceptives should not smoke. Some women should not use the Pill, including women who have or have had blood clots, certain cancers, a history of heart attack or stroke, as well as those who are or may be pregnant. The Pill does not protect against HIV or sexually transmitted diseases.

**For further safety and other information, please see the Patient Brief Summary on the reverse side and visit [www.yourpillyourchoice.com](http://www.yourpillyourchoice.com)**

Yaz and Yasmin are registered trademarks of Bayer Schering Pharma AG, Berlin, Germany.

WBC Women's Choice  
©2008 Warner Chilcott (US), LLC 28152108/50080 March 2008 Printed in USA

FIGURE 3.4: PAGE 1 OF LOESTRIN24 FE ADVERTISEMENT

The majority of the advertisement targets Yaz and its sister pill Yasmin. The main title reads “Does your birth control pill contain a recommendation for a blood test?” According to this advertisement, “your doctor may ask you to get a blood test to check your potassium level” if you take Yaz. A blue rectangular box under the paragraph states “With Loestrin 24 Fe you don’t have to worry about a blood test” though most women would benefit from a blood test to determine their risk of experiencing blood clots when taking the Pill.

Finally at the bottom of the page “Important Safety Information about Loestrin 24 Fe” is in bold letters. The safety warning reads:

*Oral contraceptives are not for everybody. Most side effects of the Pill are not serious and those that are, occur infrequently. Serious risks, which can be life threatening, include blood clots, stroke, and heart attacks, and are increased if you smoke cigarettes. **Cigarette smoking increases the risk of serious cardiovascular side effects, especially if you’re over 35. Women who use oral contraceptives should not smoke.** Some women should not use the Pill, including women who have or have had blood clots, certain cancers, a history of heart attack or stroke, as well as those who are or may be pregnant. **The Pill does not protect against HIV or sexually transmitted diseases.***

Qualifying language like “most side effects... are not serious” and “occur infrequently” and “can be life threatening” is used to downplay the risks involved in taking this medication. And the sentence ends with the disclaimer that those risks are increased if you smoke cigarettes. Here the advertisers give women a controllable factor for the side effects, making it easy for them to inaccurately conclude that “I don’t smoke, so I’m not at risk.” As stated before, it is true that women who smoke are at an increased risk, but placing that information at the end of the list of serious side effects leads women to believe that if they do not smoke, they are not at risk.

On the back of the advertisement there is one column of fairly small, dense text in the middle of the page with plenty of white space on either side (see Appendix A). In this section the wording is, for the most part, the same as that used in the other advertisements. Here the advertisement states that blood clots are a side effect of taking birth control pills. Listed with bullet points are increased risk factors for serious side effects including “have or had clotting disorders, heart attack, stroke.” However, the

advertisement provides no information concerning the symptoms of these side effects. And only makes the same weak recommendation that the other advertisements make- that women should notify their healthcare provider if they notice “any unusual physical disturbances.”

### *Summary of Advertisements*

“Risk information typically is presented in often-ignored smaller print; as part of a large, undifferentiated block of text... or simply hidden in plain view... Even when found and read, risk information often is missing key pieces of information that consumers need to evaluate drug risks” (Davis 607). Unfortunately for women this seems to be the case with advertisements for oral contraceptives.

Each of these advertisements do list blood clots as a side effect of their medication, however: Yaz and Loestrin 24 Fe infer that the risk is only for older woman and/ or those who smoke; Lybrel obscures the risk by referring to it as “adverse effects on the heart and blood vessels”; and all three use conditional qualifying language that has been shown to reduce the understanding of the risks associated with taking a medication (Davis 619).

All three advertisements mention that “had or have had clotting disorders” is a condition that increases the risk of serious side effects. However, none of them list it on the front of their advertisements. And they do not make any effort to inform women that they could have a clotting disorder and be completely unaware of it.

Additionally, none of the advertisements analyzed in this research explains symptoms of the side effects listed in their warning information. And as far as what to do

in the event of a serious side effect, all three use the vague terminology of “unusual physical disturbances” as a condition for notifying a health care provider. And this information is buried deep in the dense portions of small text.

The Lybrel and Loestrin 24 Fe advertisements contain more complete information about blood clots on the front page than Yaz, including descriptions of women who should not take the Pill. Perhaps this is one of the reasons the FDA found the Yaz advertisement lacking. But unlike Yaz and Lybrel, the Loestrin 24 Fe advertisement does not list migraines or “headache with neurological symptoms” as a risk factor, probably because this is relatively new medical information and their risk information was last revised in 2006, while the others were written in 2007.

While the legal responsibilities of the advertisers seem to have been met by the admission in the advertisements that birth control pills *can* cause clots, their ethical obligation to customers is questionable. Clearly, Yaz failed to meet either, hence their reprimand by the FDA. Unfortunately, for consumers, the FDA ruling and subsequent fine is tantamount to a slap on the wrist. What Davis et al. conclude in their article from the *Journal of Health Communication* seems to be consistent with this research. Pharmaceutical advertisers “show little inclination to clearly and completely communicate the side effects of drug usage.” And as research has shown, this is dangerous because patients exposed to advertising for medications are requesting these drugs which they understand the benefits for, but not the risks. (38, 29).

TABLE 3.1: ADVERTISEMENTS

	<b>Risk of Thrombosis</b>	<b>Symptoms of Thrombosis</b>	<b>Thrombophilia as a Risk</b>	<b>Contacting Doctor</b>
<b>Yaz</b>	Yes	No	Yes*	Yes*
<b>Lybrel</b>	Yes	No	Yes*	Yes*
<b>Loestrin24 Fe</b>	Yes	No	Yes*	Yes*

*\*inadequate information*

## WEBSITES

Websites are an increasing source of information for many women. Warner and Procaccino found that among female Web users, 94% reported that they were likely to use the Internet as a source of health information (792). Additionally, they established that women who use the Internet often were able to answer their health questions with information found online (801). If women are making health care decisions based on what information they find online, it is even more important than ever to look at the accuracy of the sites providing health information.

To choose three websites for comparison in this study, the term “birth control pills” was typed into four popular search engines (Google, AOL, MSN, Yahoo!). The table below shows the top displayed sites on January 29, 2008. All “sponsored” sites, those that have paid for placement within the search results, were omitted from this list.

TABLE 3.2: CROSS REFERENCE OF SEARCH ENGINES

SITE	AOL	GOOGLE	MSN	YAHOO!
www.healthywomen.org	X	X	X	X
www.fwhc.org	X	X		X
www.mayoclinic.com	X	X	X	X
www.plannedparenthood.org	X	X	X	X
www.youngwomenshealth.org	X	X		X
www.wdxcyber.com	X	X		
www.brown.edu	X	X	X	X
www.acog.org	X	X		
kidshealth.org	X	X		X
www.birthcontrol.com	X		X	
www.birthcontrolbuzz.com			X	
www.birthcpills.com			X	
www.mybirthcontrolstore.com			X	
www.webmd.com			X	X
www.wikipedia.org			X	X
medicinenet.com				X

Of the four matches that spanned all of the search engines the three selected for analysis were healthywomen.org, mayoclinic.com, and plannedparenthood.org. The Brown University site was found further down the search results than the other three sites, so it was eliminated. Additionally, when searching for information regarding birth control pills, the assumption could be made that the Brown University page was specifically for their students, and not necessarily relevant for other women.

Each site was given a cursory examination for usability based on Nielsen's Ten Usability Heuristics. Then, they were examined for language, content, and the accuracy of the content with regards to the four previously stated questions.



### ***Healthywomen.org***

Healthywomen.org is a website run by the National Women's Health Resource Center, a non-profit organization that "has helped women be informed health care consumers and has supported and promoted major milestones in the advancement of women's health for the past two decades." The page on this site that was located by the search engines (<http://www.healthywomen.org/healthtopics/birthcontrolpills>) is a "Health Topics" page about birth control pills.

Based on Nielsen's criteria, the site appears to be fairly well organized, with the exception of being a little cluttered (see Figure 3.5). The language used is consistent with "real-word conventions" and remains consistent throughout the webpage. Medical terms without a more common equivalent like "ectopic pregnancy" and "amenorrhea" are hyperlinked to a small pop-up box that define them. A column on the right side of the page includes links to different sections of that page, links to related stories, and a place to ask questions. There is also a place on the left side of the page titled "Related Resources," with links to books, news, web sites, etc. By providing sources for the information found on this site, healthywomen.org increases its credibility.

National Women's Health Resource Center  
 healthywomen.org

Home About NWHRC Health Topics A-Z Health Centers Publications & Resources Columns News Room

Call Us: 1-877-986-9472 (toll-free) Search Our Site Go Spell Checker

Health Topics A-Z Sign up for Free e-Newsletters

Birth Control Pills  
[Facts to Know](#)  
[Questions to Ask](#)  
[Key Q&A](#)  
[Test Your Knowledge](#)  
[References](#)  
[Medical Advisor](#)  
[Site Map](#)

A Blog is Born:  
**Notes from the Nursery**

Related Resources  
[Books \(2\)](#)  
[News \(14\)](#)  
[National Organizations \(8\)](#)  
[Web Sites \(10\)](#)  
[NWHRC Publications \(3\)](#)

Health Topics A-Z  
[Table of Contents](#)  
 -- Select Health Topic --

Health Topics A-Z Text size: A A A February 24, 2009

Birth Control Pills  
 HEALTH TOPIC

Birth Control Pills

Order NWHRC Publications

More than 45 years since the U.S. Food and Drug Administration (FDA) approved "the pill" in 1960, it continues to be the most popular and one of the most effective forms of reversible birth control ever invented. According to the Johns Hopkins School of Public Health Population Information Program, more than 18 million US women rely on birth control pills, also called oral contraceptives, as their birth control method. Today, American women have more than 40 different oral contraceptive products from which to choose.

Unlike the original oral contraceptives used decades ago, low-dose forms with few health risks are the norm. Today's birth control pills (BCPs) even offer health benefits.

Despite the fact that they are safe for most women, however, BCPs do carry some health risks. For example, if you are over 35 and smoke or have certain medical conditions such as a history of blood clots or breast or endometrial cancer, your health care professional may advise against taking BCPs. Also, birth control pills do not protect you from sexually transmitted infections (STIs), including HIV (human immunodeficiency virus), the virus that causes AIDS.

In recent years, birth control pills have been changed to include less hormones, resulting in fewer side effects. In fact, all healthy women who don't smoke may use birth control pills, regardless of their age.

Unlike other forms of birth control sold over-the-counter, you need a health care

**What you need to know:**  
[How Birth Control Pills Work](#)  
[Types of Birth Control Pills](#)  
[Emergency Contraception](#)  
[Benefits and Risks](#)  
[Possible Drug Interactions](#)

**Related Stories:**  
[Your Menstrual Cycle: How it Works, How to Manage it](#)  
[Contraception: What's Next?](#)  
[Turning 40? Review Your Contraception Options](#)  
[Firing Up Sexual Desire](#)  
[Sex and Your Teen](#)  
[STDs: It could be you](#)

**Still have questions?**  
[Ask the Sexual Health Expert](#)

FIGURE 3.5: BIRTH CONTROL PILL PAGE FROM HEALTHYWOMEN.ORG

The first section, which might be considered an overview or introduction about birth control pills (though it is not labeled as such), contains two interesting parts. The following information is in the first paragraph:

*Despite the fact that they are safe for most women, however, BCPs do carry some health risks. For example, if you are over 35 and smoke or have certain medical conditions such as a history of blood clots or breast or endometrial cancer, your health care professional may advise against taking BCPs.*

While this warning is accurate, their example of “if you are over 35 and smoke” could lead younger, non-smokers to believe that there is no risk for them. Since most women begin taking birth control pills before the age of 24, many may dismiss this warning as not pertaining to them. And while it is important that they mention a history of blood clots as a warning, many women who have FVL have no family history indicative of this risk.

The second part of the opening section incorrectly states:

*In recent years, birth control pills have been changed to include less hormones, resulting in fewer side effects. In fact, all healthy women who don't smoke may use birth control pills, regardless of their age.*

While many birth control pills have no side effects in certain women, all birth control pills have dangerous side effects. And furthermore, there are no pills that “all healthy women who don’t smoke” may take. I can only assume that the mythical “safe pills” the website is referring to are progestogen based pills, which are commonly thought to be safe for women who cannot use estrogen. However, “studies have shown that both the estrogen dose as well as the progestogen type of oral contraceptives contribute to the increased risk of venous thrombosis in oral contraceptive users” (Vliet 563).

Further down the page, the site lists different types of pills and their possible side effects. Under the heading “Combination Pills,” three different types are listed, all containing estrogen. Following a short description of each type of pill is a list of advantages, disadvantages, and possible side effects, in that order. Fifteen advantages are listed, including a reduction in the risk of ovarian and endometrial cancer. Scientists are

finding this is no longer a benefit of the pill, since recent studies indicate that taking the pill increases the risk of other types of cancer including breast cancer (Szabo).

Only four disadvantages are listed:

- *could cause nausea, vomiting, headaches and/or spotting, particularly with the first few cycles*
- *may lead to hypertension (less than one in 200 women)*
- *may cause blood clots in a small percentage of users*
- *may contribute to the formation of gallstones and rare benign liver tumors*

All of the disadvantages of taking the pill are tempered with qualifying conditional terms like “may contribute to” and “could cause.” Each of the disadvantages is further modified to appear less dangerous by adding phrases like “in a small percentage of users” to the thrombosis risk and “rare benign” to the liver tumors risk.

Contrarily, these same qualifying phrases are not used to describe the benefits. Certainly birth control pills do not improve acne, have beneficial effects on cholesterol, and decrease pain and cramps in *all* women. Why should the advantages be described as benefits applicable to every woman who takes the pill, but the disadvantages are relegated to just a select few? This practice of using qualifying languages is perhaps not surprising when used in pharmaceutical advertising, after all, it is in their best interest to provide the most optimistic view of their product and therefore increase profits. However, this use of qualifying language on a not-for-profit website that claims to provide women with accurate health care information is questionable.

Toward the end of the web page is a section called *Health benefits, risks and other medical issues about birth control pills*. In this final section, the website does a much better job of addressing the risks. Here, the site discusses ischemic strokes, VTEs, and also the connection between migraines and stroke. VTEs are described:

*This rare condition causes clots to form in your blood vessels and can cause symptoms including pain, swelling, and varicose veins, and may block the flow of blood. The risk may vary with the type of progestin used in the pill.*

The mention of risk with progestin pill is surprising since earlier on the page, the site fails to include VTE as a risk with progestin pills. It is also unfortunate that they list VTEs as a “rare condition,” since according to the U.S. Surgeon General they affect as many as 600,000 people a year. And also unfortunate is the site’s description of the symptoms of a blood clot, which fail to address symptoms that indicate anything other than a deep vein thrombosis.

In addition to listing VTEs as a risk when taking birth control pills, healthywomen.org also lists having migraines as increasing the risk of stroke:

***Migraines and stroke.** Women who take oral contraceptive and have a history of migraines have an increased risk of stroke compared to nonusers with a history of migraine. Your risk is greatest if you have migraines with "aura"--neurologic symptoms related to vision, such as blurred vision, temporary loss of vision or seeing flashing lights or zigzag lines. As a result, both the American College of Obstetricians and Gynecologists (ACOG) and the World Health Organization (WHO) have concluded that for women over age 35 who get migraines, the risks of BCPs use usually outweigh the benefits.*

This information is only partly accurate. However it fails to mention that, according to the World Health Organization, women who suffer migraines with aura should not take birth control pills at any age (Allais S12). The way they phrase the warning leads women to believe that danger is only for women over 35, a recurring theme in birth control pill information.

Overall, [healthywomen.org](http://healthywomen.org) does list blood clots as a side effect of birth control pills. However, the site fails to address clotting disorders, or to properly explain the symptoms of a blood clot, listing only those associated with DVTs. The site does not emphasize the dangers of blood clots and, consequently fails to advise women what to do if they have a clot. It also perpetuates the myth that certain risks are only associated with older women. Regrettably, this website designed to serve the interests of women downplays the risks of birth control pills in favor of highlighting advantages that may or may not be applicable for any women, let alone most women.

***[www.mayoclinic.com](http://www.mayoclinic.com)***

The Mayo Clinic is self-described as “the world’s first and largest integrated, not-for-profit group medical practice.” The second most popular webpage, after cross-referencing search engines, is their “Birth control pill FAQ: Benefits, risks and choices” (<http://www.mayoclinic.com/health/birth-control-pill/WO00098>) page. As the title infers, this page is set up in a question and answer format. At the bottom of the page, there are a series of links under the title “Related.” The site appears to meet Nielsen’s criteria for usability, with the aesthetics of the page’s minimalist layout (see Figure 3.6). The information is written in terms familiar to most readers and is consistent throughout the webpage. With the exception of the lack of information provided, the site is well designed.

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WOMEN'S HEALTH

Feb 26, 2009

## Birth control pill FAQ: Benefits, risks and choices

How are pills that prevent your period different from regular birth control pills? Will taking the pill prevent menopause? Here are the answers.

If you use the birth control pill — that is, an oral contraceptive — you're probably happy with its convenience and reliability. Still, you may have many questions about the potential effects of birth control pills on your overall health. Here's what Mayo Clinic specialists have to say about women's health and oral contraceptive use.

**How do pills that eliminate some or all your periods differ from other birth control pills?**

Traditional birth control pills make your reproductive system mimic a regular 28-day monthly cycle. For the first 21 days, you take active pills containing reproductive hormones. For the last seven days, you take a placebo. While you're taking the placebo pills, you bleed vaginally, as if you were having a regular menstrual period.

By contrast, extended-cycle birth control pills contain active hormones for every day of the month. The newest extended-cycle regimen, Lybrel, is a low-dose pill that's designed to be taken continuously for one year, with no breaks for hormone-free intervals. Lybrel is meant to suppress all menstrual bleeding.

Two other specially designed, extended-cycle pill regimens — Seasonale and Seasonique — are also currently on the market. With both pills, you take active hormone pills every day for three months, then you take one week of placebo pills (Seasonale) or low-dose estrogen pills (Seasonique). You'll experience menstrual bleeding during that week.

**Can you use ordinary birth control pills continuously to prevent having a period?**

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FIGURE 3.6: BIRTH CONTROL PILL PAGE FROM MAYOCLINIC.COM

This page appears to be targeted toward women who are already on birth control pills, as is indicated in the first paragraph:

*If you use the birth control pill — that is, an oral contraceptive — you're probably happy with its convenience and reliability. Still, you may have many questions about the potential effects of birth control pills on your overall health. Here's what Mayo Clinic specialists have to say about women's health and oral contraceptive use.*

The first ten questions address concerns that women currently taking birth control pills may have. In fact, out of the 17 questions on the webpage, only five address adverse side effects from taking the pill. These five questions (in order) concern weight gain, risk of

cancer, cholesterol levels, blood pressure, and the final health question “What’s the risk of smoking if you’re over age 35 and taking birth control pills?”

Unfortunately, the smoking question is the closest this site gets to informing women about the risks of blood clots. The Mayo Clinic’s response to the question is simply that smoking can increase the risk of cardiovascular disease. And by phrasing the question on their information page about “Benefits, risks, and choices,” the brief nod the site gives to cardiovascular issues is just another example of attributing the dangers of birth control pills only to those who smoke and/or are over 35.

Nowhere on this page does it mention thrombosis as a risk when taking birth control pills. Therefore, it’s not surprising that the site also fails to mention anything about clotting disorders increasing the risk of blood clots, the symptoms of a blood clot, or what a woman should do in the event of a blood clot. Even the related links at the bottom of the page do not give women the opportunity to find more information about risks involved with taking birth control pills. Overall, this site fails to adequately inform women of any risks associated with taking birth control pills and is a poor representation of information from “the world’s first and largest integrated, not-for-profit group medical practice.”

***[www.plannedparenthood.org](http://www.plannedparenthood.org)***

The Planned Parenthood site is the third site that was reviewed. According to this site, Planned Parenthood “is the nation’s leading sexual and reproductive health care advocate and provider.” As listed on this website, Planned Parenthood offers “medically accurate information.” The page on this site that was reviewed is entitled “Birth Control



Pill (<http://www.plannedparenthood.org/health-topics/birth-control/birth-control-pill-4228.htm>).

The design of this website meets Nielsen’s usability criteria. The page layout is simple and easy to navigate. It links relevant text to similar pages to give readers access to further information, making the site flexible and efficient. At the top of the page is a link entitled “Legal Disclaimer” which leads to the warning “Information Obtained Through the PPFA Web Site Does Not Constitute Medical, Legal, or Other Professional Advice.”



FIGURE 3.7: BIRTH CONTROL PILL PAGE FROM PLANNEDPARENTHOOD.ORG

On the left side of the webpage are links to information about other birth control options. Just under the title of the Birth Control Pill page there is a “Quick Facts” box with four bullet points. The second bullet point states that birth control pills are “Safe,

effective, and convenient” with each of those terms linking to a spot further down on the same page. Following the “Quick Facts” box is an introductory paragraph and a “Highlights” section with bullet points that link to each different section of the webpage. Each of the following sections are formatted as question and answers.

Under the “How Safe Are Birth Control Pills?” section, the first paragraph states, accurately, that most women can use birth control pills safely. The second paragraph informs women that all medications have risks and that “Certain conditions” can increase those risks. “Certain conditions” is hyperlinked to a page titled “Who Can Take Birth Control Pills?”

This page lists conditions in which a woman should not take birth control pills. Among these conditions is “have certain inherited blood-clotting disorders.” It further states that women with clotting problems should not take birth control pills, even progestin-only pills, and that migraines increase the risk factors. At the end of this page, there is a link to “other methods” of birth control.

Under the “What Are the Benefits of Birth Control Pills?” section, Planned Parenthood states that birth control pills can offer “some protection against” followed by a list including acne, ovarian cysts, etc. By using qualifying language in the benefits section of the birth control pill information, this site is offering women a more accurate interpretation of health benefits than if they had stated that birth control pills do prevent acne, ovarian cysts, etc.

Planned Parenthood splits the disadvantages information into two sections: “Possible Side Effects” and “Serious Side Effects.” Under the serious side effects, they list heart attack, stroke, having a blood clot in the legs, lungs, heart, or brain. Below those

risks, they list factors that increase those risks, including “certain inherited blood-clotting disorders.”

Also in the serious side effects section, the site lists warning signs and suggests that women report any of the warning signs to their doctor as soon as possible. The list of warning signs includes symptoms of strokes, breast cancer, heart attack, pulmonary embolism, and deep-vein thrombosis, as well as others.

Impressively, the Planned Parenthood site seems to clearly and accurately present information about birth control pills. The risk of thrombosis is stated and thrombophilia is mentioned as a precaution. The site also describes the symptoms of a blood clot and instructs women to contact their doctor should they have any symptoms. Additionally, the site fairly represents the benefits and other risks of taking birth control pills.

The Planned Parenthood site could be improved by linking the phrase “certain inherited blood-clotting disorders” to a page that more thoroughly discusses thrombophilia. They could emphasize that women with symptoms should seek medical attention immediately. The phrasing “report any signs to your health care provider as soon as possible” could be misinterpreted that you should tell your doctor at your next appointment, instead of that you should see a doctor or go to the hospital immediately. These suggestions aside, the Planned Parenthood webpage on birth control pills lives up to their claim to provide “medically accurate information.”

### ***Summary of Websites***

Despite all ranking high on popular search engines, the sites reviewed vary greatly on the amount and accuracy of the information they provide. Clearly, the Mayo

Clinic’s website is the most lacking, with no meaningful risk information of any kind. On the other hand, at least it does not provide inaccurate and conflicting information like healthywomen.org. Healthywomen.org did warn women that blood clots are a risk factor when taking birth control pills, but it overstated their health benefits. And it perpetuated the misconception that only older women or those that smoke are at risk when taking birth control pills.

The Planned Parenthood site, the only site with a legal disclaimer to let women know their information was not a substitute for medical counsel, had the most accurate information. Ironically, the other two sites listed inadequate and even incorrect risk information yet provided no such disclaimer. Of course, there is always room for improvement, particularly with regard to informing women about inherited thrombophilia. However, when compared to the other sites in this study, the Planned Parenthood is unquestionably the best source of risk information.

TABLE 3.3: WEBSITES

	<b>Risk of Thrombosis</b>	<b>Symptoms of Thrombosis</b>	<b>Thrombophilia as a Risk</b>	<b>Contacting Doctor</b>
<b>Healthywomen.org</b>	Yes	Yes*	No	No
<b>Mayoclinic.com</b>	No	No	No	No
<b>Plannedparenthood.org</b>	Yes	Yes	Yes	Yes

*\*inadequate information*

## INSERTS

Pharmaceutical inserts were collected and analyzed for three different types of birth control pills (see Appendix A). These materials were obtained from women who received them with their prescriptions that were filled between December 2008 and

January 2009. The inserts were acquired in this manner to ensure that they are an actual representation of what women receive with their prescription.

***Nortrel (norethindrone and ethinyl estradiol tablets, USP)***

The Nortrel tablets are produced by Barr Laboratories, Inc. and the prescription was filled at a student health center on the campus of a major university. The pill insert has a revision date of March 2005. The insert folds out to a single piece of paper about 12 by 17 inches, with a 12 by 4 inch section separated by perforation. This smaller section is perforated and labeled “Brief Summary Patient Package Insert” and has text on the front and back of the page.

On the main section of the insert, there is also text on the front and back. The text on the front is dedicated to precautions for taking the pill. Like in the advertisements, the risk of blood clots in women over 35 who smoke is highlighted with bold, boxed text. Under the heading “Who Should Not Take Oral Contraceptives:” it states “you should not use the pill if you have any of the following conditions” followed by a list including a *history* of heart attack or stroke; blood clots in the legs, lungs or eyes; or a *history* of blood clots in the deep veins of your legs. This information could lead one to believe that you are only at risk, had you ever previously suffered from any of these conditions. It fails to list any information about family history or clotting disorders. The insert also fails to list migraines with aura under these conditions, but does list it as a condition to speak to your health care provider about before taking OC.

Further into this section is a chart that estimates the risk of death from birth control use. However, the risk of thromboembolic incident with oral contraceptive use is

not provided in a chart, only in the middle of a brief and dense paragraph under “Risk of developing blood clots.” Under, the chart is a “Warning Signals” section that lists symptoms of blood clots, including those for stroke, deep vein thrombosis, heart attack, and pulmonary embolism. If any of these symptoms occur, the manufacturer advises you to call your doctor immediately. All of this information is listed in the same font. Only the section headings are bolded.

The smaller section is perforated, presumably so women may tear it away from the larger section to keep. The majority of the smaller section, approximately three quarters of the text, is dedicated to instructions for how to use the pill, including what to do if you miss a pill. The remaining quarter is an abbreviated warning. This warning does mention clotting disorders and risk of blood clot. However, there is no mention of symptoms. And as far as what to do if you experience symptoms, the inserts use the same weak language from the advertisements, to “notify your doctor” if you have “unusual physical disturbances.”

Overall, the Nortrel insert contains all four pieces of information: blood clots are a risk; clotting disorders increase this risk; symptoms of a blood clot; and contact a healthcare provider in the event of these symptoms. However the main portion of Nortrel insert fails to list clotting disorders as an increased risk factor. While the smaller section, the one perforated to make it easy to keep, fails to list symptoms of a blood clot and provides inadequate guidance in the event of side effects.

***Tri-Sprintec 28 (norgestimate and ethinyl estradiol tablets)***

The Tri-Sprintec tablets are also produced by Barr Laboratories, Inc. and this prescription was filled at a CVS pharmacy in Tallahassee, Florida. Though similar in appearance to the Nortrel, and from the same manufacturer, this pill insert has a revision date of February 2004.

Even though the Nortrel was revised over a year after the Tri-Sprintec 28 revision, the warning information is exactly the same. The only differences between the two inserts are the logos and chemical make up of each set of pills. Clearly the manufacturer did not see any reason to make any actual changes to the warning information from 2004 to 2005. They also felt no need to update the information for these prescriptions with any new information from the past four to five years. Hence no warning about migraine with auras despite the fact that, as previously mentioned, the World Health Organization stated “that women suffering from migraine with aura at any age should never use oral contraceptives” (Allais S12). Perhaps it was not cost effective to update these leaflets

***Loestrin 24 Fe (norethindrone acetate and ethinyl estradiol tablets, USP and ferrous fumarate tablets)***

The Loestrin tablets are produced by Warner Chilcott and this prescription was filled at a student health center at a major university. The pill insert is dated September 2007 and measures 11 by 20 inches. A portion (3 by 20 inches) of the insert is perforated, presumably so the patient can remove this section to keep.

The font used for this insert is larger than the font of the other two inserts, with the main section considerably larger and the smaller section only slightly larger. The

information contained in the insert is formatted almost identically to the other two. Like the others, in the main section the risk of blood clots in smokers who are over 35 years of age is in a separate box from the other warning information and is in bold font. Indicating that women who are over 35 or smoke are those who should receive the most emphasized and therefore visible warning information.

One difference can be found under the “Who Should Not Take Oral Contraceptives” section. Here Loestrin24 Fe lists seven more conditions than the other inserts, none of which concern cardiovascular conditions. This insert fails to list a family history of blood clots or clotting disorders as an increased risk factor. Unfortunately, the advisement that women should not use the pill if they have or have ever had a history of blood clots, could lead women to believe that if they have never had a blood clot, then they are not at an increased risk.

Though from a different manufacturer, the rest of the materials in the insert are nearly identical, including the warning signals. Like the other two inserts, the smaller, tear-away section lists clotting disorders as an increased risk factor. But also like the other inserts, it fails to list the symptoms, referring to the main section that was presumably disposed of by the women who tore off the perforated section to keep.

### ***Summary of Inserts***

In conclusion, all of the birth control inserts have the same strengths and weaknesses, though the Loestrin24 Fe provides the information in larger font that is much more readable than Nortrel and Tri-Sprintec. These inserts also offer considerably more information than the advertisements and use fewer conditional terms. Technically, each



of the inserts lists all four points of information that were examined in this study. However, clotting disorders are only mentioned in the smaller sections, while symptoms of blood clots are only listed in the larger sections. This means one would have to thoroughly read both sections of the inserts to obtain all of the risk information- something that is unlikely due to the redundancy of much of the rest of the information.

Each insert has statistical information about the risks involved with taking the medication but without the disclaimer that it is based on studies run by the very company who makes the birth control pill. There is actually no mention about what studies have provided this information. Kemmerman et al. found that studies funded by pharmaceutical companies that make oral contraceptives produced more favorable results than independent studies of the same medications (133). And as previously mentioned, it is not likely that most women would even understand the statistics presented. The recent study by Gigerenzer et al. demonstrated the statistical illiteracy of most patients and, more alarmingly, their physicians.

Besides the typical problems with understanding medical warnings (tiny print, obscure statistics), these inserts fail to make clear the increased risk of blood clots due to clotting disorders. The pharmaceutical manufacturers need to use language that not only more clearly defines risks and symptoms of blood clots, but also indicates that there is a possibility that women may have a clotting disorder and be unaware.

Finally, one of the central tenets of technical communication is to consider your audience and design accordingly. As Schriver points out in *Dynamics in Document Design*, “Since people rely on documents to make decisions that influence their safety, livelihood, health, and education, the highest ethical standards must be brought to bear in

making textual choices- in deciding what to say and what not to say” (11). By creating documents that are so text heavy, with dense language couched in conditional terms, in font barely large enough to read, pharmaceutical companies are clearly not designing for their audience, or any audience for that matter. But perhaps that is their intention.

TABLE 3.4: PHARMACEUTICAL INSERTS- MAIN SECTION

	<b>Risk of Thrombosis</b>	<b>Symptoms of Thrombosis</b>	<b>Thrombophilia as a Risk</b>	<b>Contacting Doctor</b>
<b>Nortrel</b>	Yes	Yes	No	Yes
<b>Tri-Sprintec 28</b>	Yes	Yes	No	Yes
<b>Loestrin24 Fe</b>	Yes	Yes	No	Yes

TABLE 3.5: PHARMACEUTICAL INSERTS- SMALL SECTION

	<b>Risk of Thrombosis</b>	<b>Symptoms of Thrombosis</b>	<b>Thrombophilia as a Risk</b>	<b>Contacting Doctor</b>
<b>Nortrel</b>	Yes	No	Yes	Yes*
<b>Tri-Sprintec 28</b>	Yes	No	Yes	Yes*
<b>Loestrin24 Fe</b>	Yes	No	Yes	Yes*

*\*inadequate information*

## DISCUSSION

This analysis of the media used to communicate risk information about side effects of birth control pills found that it would be very difficult for women to find exceptional sources of information. In many cases, it would difficult to for them to find even adequate information. For example, the risk information communicated in advertisements for OC is limited and sometimes downright deceptive. The increased risk

of side effects when smoking and/or over the age of 35 and the lack of protection from STDs are the only risks that are highlighted. This could be due to the increased risk factor from smoking, but it may also have to do with perception of message. Darren Shickle, in his article “*On a supposed right to lie [to the public] from benevolent motives*”: *Communicating health risks to the public*, mentions risk factors that are perceived by the public as more worrying. Chief among them is if a risk is “involuntary (e.g. exposure to pollution) rather than voluntary (e.g. smoking)” ( 245). Is it possible that pharmaceuticals want to emphasize the increased risk factors associated with taking birth control pills and smoking, thereby deemphasizing involuntary risk factors like clotting disorders?

Websites, claiming to be non-profit sources of information for women often list incomplete information, or in the case of healthywomen.org, inaccurate information. They use conditional terms that seem to favor birth control pills, while claiming only to have an agenda to help women make educated decisions about their health. Much of their warning information is similar to that found in the inserts and advertisements produced by the pharmaceutical companies themselves, certainly not a neutral source.

In their inserts, pharmaceutical companies couch their risk information in text heavy documents of barely readable font full of conditional language. Like the advertisements, they highlight only controllable risk factors. These inserts are created to be accountable to their legal teams but not to their patients.

With the exception of PlannedParenthood.org, all of the media analyzed here was lacking adequate, and in some cases accurate information about blood clots, their symptoms, clotting disorders, or what to do in the event of a blood clot.

## CHAPTER FOUR

### SURVEY

After demonstrating the limited information available to women in the media analysis, this survey attempted to discern what women actually know about blood clots and clotting disorders. The survey included 23 questions (multiple choice, fill-in-the-blank, ranking) and one open-ended comment section, and assessed what women know about the risks of OC. The survey was broken down into 5 sections (“pages”) and was hosted on SurveyMonkey.com. The first page, titled “Survey Information,” was an IRB approved disclaimer and contained no questions. The second page was titled “Birth Control Pill Survey,” contained six questions, and asked when, where, and why women were prescribed birth control pills. This page also contained a question about whether healthcare providers offered women other options besides birth control pills.

The third page of the survey was entitled “Risks” and contained questions about the women’s interactions with pharmacists and their healthcare providers with regard to risk information. This section also contained two questions to gauge the women’s understanding of which health risks are associated with taking birth control pills. Women were asked to select which health risks out of 11 possible choices are associated with birth control pills. The list of health risks used for this survey was taken primarily from Bryden and Fletcher’s 2001 study; though for this survey, women were also given the option to select “None of the above” or “Don’t know.”

The fourth page of the survey, “Communication,” asked the women three questions about their behavior concerning the information that accompanies their prescriptions- whether from the pharmacy or the pharmaceutical company.

The fifth, and final, page of the survey was called “Awareness,” contained eight questions and a final comment section. These questions addressed whether the women were familiar with inherited thrombophilia (i.e. FVL), familiar with the symptoms of blood clots, and whether they would be willing to take a blood test to assess their own risk for clots.

## **PARTICIPANTS**

The survey was created using SurveyMonkey.com and then tested by a usability professional. Her suggestions, mostly changes in wording for clarification, were put into place. The survey went live at approximately 12:30pm on Tuesday, February 10<sup>th</sup>. Responses were solicited through email networking and the website Facebook.com. Due to the subject matter, response to the survey was staggering and immediate. After being posted for only four hours, 100 surveys had been completed. The survey remained live for 10 days, collecting a total of 325 surveys with only one participant that skipped all of the questions, and 311 that answered all questions requiring an answer.

## **RESULTS**

### ***Birth Control Pill Survey***

The average age of the women surveyed when they first began taking birth control pills was a little under 19 years (18.9). Of the 324 women who responded, only 20 or 6% were over the age of 25 when they first began taking birth control pills. A little over half (168) of the women were currently taking birth control pills when they took the survey.

Most of the women were prescribed birth control pills by their gynecologist (53.4%). A handful of the “Other” responses indicated that women had been prescribed OC by their dermatologist. One woman volunteered that she got them “from a friend.”

More than half of the women said the main reason they were prescribed birth control pills is because they asked for a prescription. And over thirty percent were prescribed them for reasons other than birth control (regulate periods, clear up acne, etc.) with one woman responding that the “Doctor suggested they would improve my skin (not true).”

When asked if their health care provider discussed any other birth control options with them, prior to prescribing the pill, five of the 324 women who answered could not remember. A handful of other women (8) felt that the question was not applicable to them because they were not prescribed the medication for birth control, or as the woman above stated, she got them from a friend. Of the remaining 311 women surveyed, 200 answered that their health care provider did not discuss other options with them.

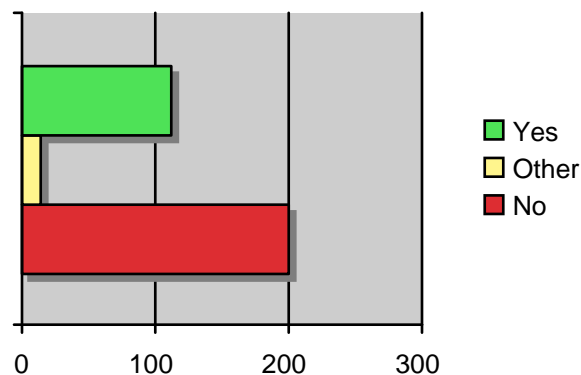


FIGURE 4.1: HEALTH CARE PROVIDERS THAT DISCUSSED OTHER OPTIONS PRIOR TO PRESCRIBING OC.

**Risks**

When asked whether their family history was taken prior to being prescribed birth control pills 85% responded yes, with 12 women choosing to skip the question. The majority of the women said that they filled out a form, while only 42.9% said they filled out a form and their health care provider discussed it with them (of 275 responses). Nineteen women chose the “Other” option on the survey with 8 who did not remember; 7 said their doctors discussed it with them but filled out no form; 2 were adopted; 1 was not asked; and 1 said that her doctor knew her family as both her mother and grandmother were also his patients.

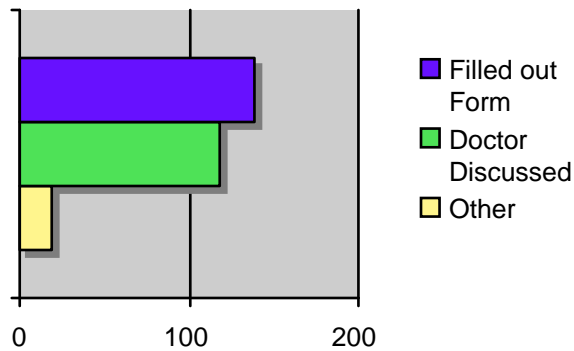


FIGURE 4.2: HOW WERE YOU ASKED ABOUT YOUR FAMILY HISTORY?

When the women were asked to select which risk factors were associated with birth control pills, most women, 76.7% of the 313 who answered the question, selected blood clots. Weight gain, which is not considered a health risk or even a side effect of birth control pills, was the selection most chosen (79.9%).

Of the risk factors listed in Figure 4.3 only the following are actually associated with taking OC:

- Increased blood pressure
- Nausea
- Stroke
- Increased risk of cervical cancer
- Increased risk of breast cancer
- Blood clots
- Heart attack


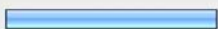



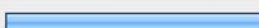


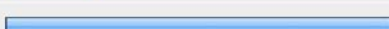

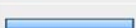


		Response Percent	Response Count
Increased blood pressure		52.4%	164
Nausea		41.9%	131
Increased risk of ovarian cancer		16.0%	50
Weight gain		79.9%	250
Increased risk for ectopic pregnancy		19.2%	60
Stroke		50.5%	158
Increased risk of cervical cancer		11.8%	37
Increased risk of breast cancer		18.5%	58
Blood clots		76.7%	240
Increased menstrual bleeding		7.0%	22
Heart attack		24.9%	78
None of the above		1.0%	3
Don't know		7.0%	22

FIGURE 4.3: RESPONSES TO HEALTH RISKS ASSOCIATED WITH OC.



Alarming, only seven women correctly chose all of the health risks. And of those seven women, six also selected options that are not health risks associated with OC. Therefore, only one woman out of 313 was able to correctly identify all of the risk factors listed.

Thirty percent of the women surveyed believed that stroke and blood clots are only risk factors for women who are over 35 and/or smoke. A little over forty percent knew that all women are at risk, but only 5 of the 7 women who correctly chose the risk factors mentioned above selected this option.

When asked if their health care provider discussed the risks of taking birth control pills with them before giving them the prescription, 54.6% (out of 313) said yes and 38% said no. Six percent of women couldn't remember. And one woman was "told to read the pamphlet for the pills to be aware of the risks." But when asked if their pharmacist discussed the risks with them, a whopping 86.9% said no. One woman said, "I received a free sample so did not go to Pharmacy. Discontinued use on day 11 due to reaction to pill (stroke-like symptoms)." And another "They had me sign a release form confirming I had received counsel from them, but I really had not."

### ***Communication***

Most women say they read the pharmaceutical insert that came with their birth control pills with 39% (of 313) claiming they read the materials thoroughly and 37.1% admitting they only glanced at the materials. The remaining women did not read the materials, read only the parts concerning missing a pill, or could not remember.

As far as materials from the pharmacy, 30.7% claimed to read them thoroughly, 30% said they glanced at them, and 22% responded that they did not read them. Four of

313 women received OC as a sample and 33 said no materials accompanied their prescriptions. When asked if they normally read the materials accompanying their prescriptions, only 30% said they read everything given to them. Nearly the same number (28.8%) said they only read the materials if they are unfamiliar with the medication. And 11.5% said they don't read the information, they trust their doctor or pharmacist to tell them the risks. One woman observed that she does not typically read the materials that come with her prescriptions as "It's dense information and not presented in an easy-to-digest format."

### ***Awareness***

When asked if the women were aware of genetic conditions that increase the risk of blood clots 58.2% (of the 311 who answered) said no. The majority of women that had heard of clotting disorders did not know about them before they began taking OC. Therefore 82.6% of women were not aware of thrombophilia before they began taking birth control pills.

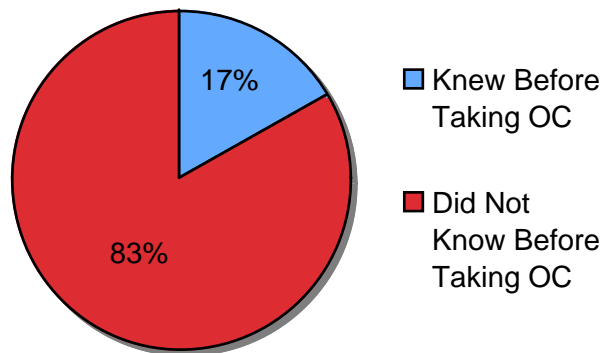


FIGURE 4.4: WOMEN AWARE OF THROMBOPHILIA.

Of the women who were aware, most say they were told by their doctors (27.7%). Others learned from a friend, read about it on the Internet, found out from the news, or learned about it in school (medical or otherwise). Twenty-one women had a family member or friend with a clotting disorder and two of the participants learned about clotting disorders because they had suffered clots, themselves. Interestingly, one woman said she came “from a family of Drs, so got tested before I began taking the pills.”

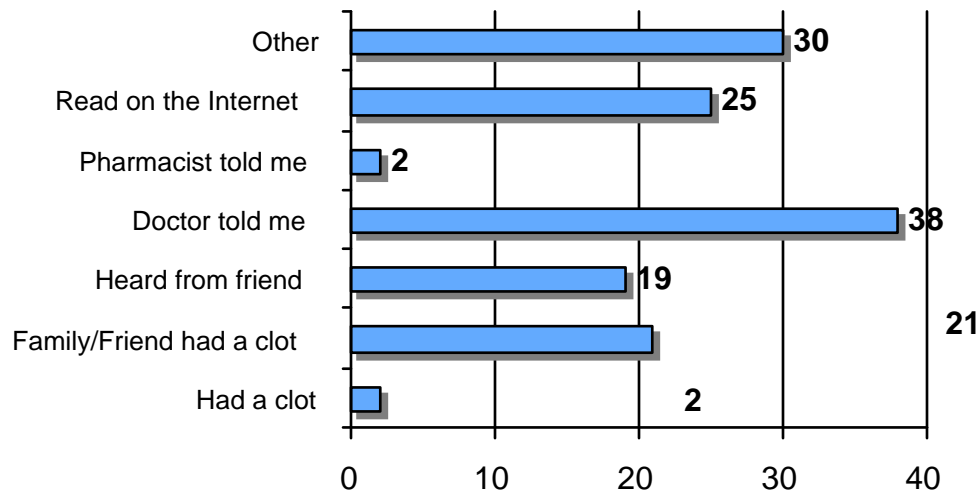


FIGURE 4.5: HOW WOMEN BECAME AWARE OF THROMBOPHILIA.

When asked whether they were familiar with the symptoms of a blood clot, most women (60.5% of the 311 who answered) admitted that they were not. Only 15.8% answered that they did know the symptoms with the remaining 23.8% unsure. When asked where they learned the symptoms of a blood clot, 9 of the 65 respondents answered that they did not know or weren't sure. The remainder said they learned from reading pamphlets or on the Internet, from a friend, or because they are in the medical field. Eight women answered that they learned the symptoms because a family member or friend had

a blood clot. And two participants said they had blood clots with one stating “When I experienced chest pain and did research online. It turned out that I had pulmonary embolisms (while on BCP).” Only 9% women reported learning about the symptoms of blood clots from their doctor. Ironically, more women know someone who has had a clot.

When the women were asked to rank where they were most likely to obtain medical information from, 54.5% listed their health care provider as their first choice. The Internet was the second most popular source of information with 37.8% listing it as a first choice and another 30% as a second choice. Friends and pharmacist were the least likely choices.

And finally, when asked if they would be willing to take a blood test to assess whether they were at an increased risk for blood clots, the women overwhelmingly said yes. Of the 311 who answered the question, 82.3% (or 256) said they would be willing to take the test. Only 7.2% said no, with the other 10.6% “not sure.”

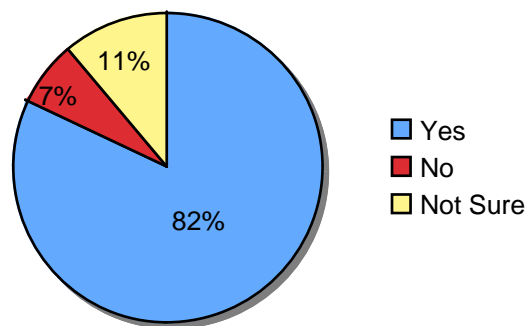


FIGURE 4.6: ARE WOMEN WILLING TO TAKE A BLOOD TEST TO ASSESS THEIR RISK OF BLOOD CLOTS?

To assess how willing women would be to pay for the blood test, they were given the following question to which 287 responded.

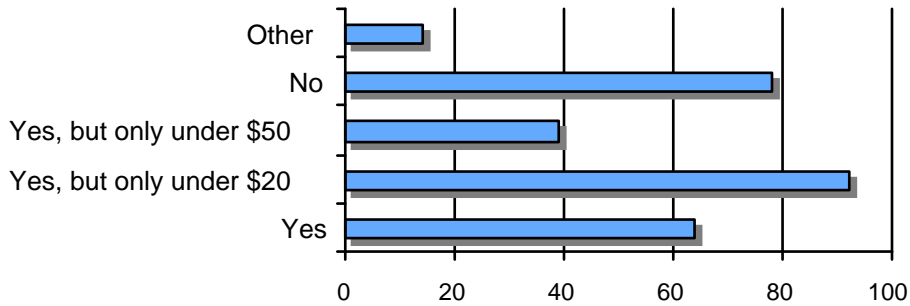


FIGURE 4.7: WOULD WOMEN BE WILLING TO PAY FOR THE TEST?

Of the 16 “Other” answers 11 answered yes with stipulations (cost, recommended by doctor, etc.). One woman said she would be willing to pay for the test if it were less than \$250 while another said \$150. The remaining five said they didn’t know if they were willing to pay for the test. Based on these results, if the blood test were under \$20, 67.9% would be willing to take the test and pay for it. If over \$20 but under \$50, that number drops only to 64.1%.

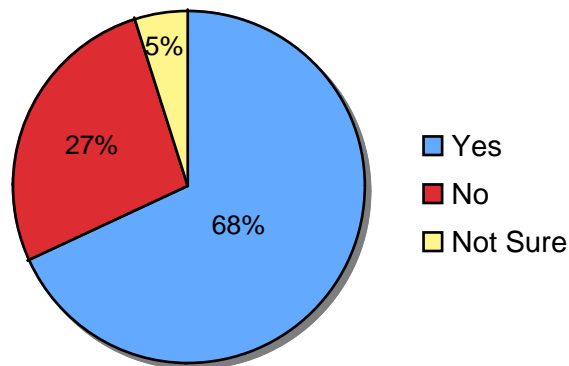


FIGURE 4.8: WOMEN WILLING TO PAY FOR THE TEST IF IT WERE UNDER \$20.

In the final section, the surveyed women were invited to “share anything else about your experience taking birth control pills.” In this section, 81 women, or 26% of survey participants responded. Their answers varied from three word responses like “severe mood swings” and “had no problems” to 400 word essays. The average length of the responses was 3.3 sentences. I reviewed all the responses in this section and categorized each as either a positive experience with birth control pills, a negative experience with birth control pills, or neutral. Out of the 81 responses, 53% were negative, 15% were positive, and the other 32% were neutral.

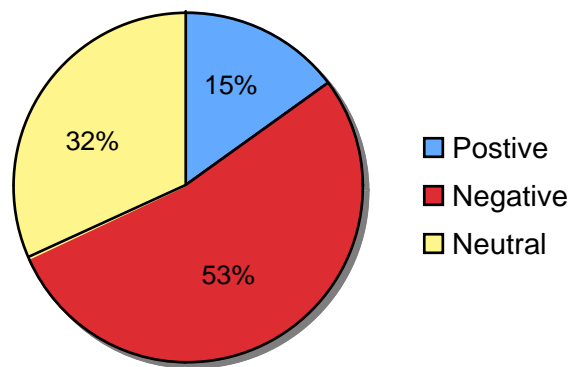


FIGURE 4.9: COMMENTS ABOUT EXPERIENCES WITH OC.

Of the negative responses, four women experienced blood clots, or symptoms of blood clots (undiagnosed) when taking the pill. One woman mentioned a family history of blood clots, while another said that she stopped taking birth control pills because she was miserable and “because I learned of two friends who had strokes after taking a form of BC.” A third woman responded, “After I had been taking BC pills for about 3 month I heard of a friend who had blood clots from it and then I re-read the pamphlet. I would

LOVE it if there was a way for me to know how much at risk I am for something like blood clots.”

Most of the other negative responses were regarding other side effects of birth control pills, especially mood swings. Some of the more candid responses included “they made me a moody [expletive]!” Another expounded on her experience with the following:

*My experience on birth control pills, the Nuvaring, or Depo-Provera all proved to be horrendous... I think birth control pills came straight from hell and I hate, hate, hate it. I would rather undergo Chinese water torture daily than take birth control, and that is the God's honest truth... My fertility has been affected forever by my under informed choice to go on birth control, and by the irresponsible doctors who encouraged me to switch methods rapidly “until I found what worked for me.”*

Disturbingly, many of the negative responses focused less on the participants' actual experience with birth control pills, and more on their experience with their doctors.

Comments from these women included:

- *My current gynecologist completely downplayed any risks associated with hormonally-based birth control, so I do not trust her (or most doctors for that matter).*
- *I wondered after being on the pill so long if there were any affects, but have had difficulty getting doctors to even discuss this.*
- *It was never explained why the particular prescription I was given was chosen over other available options/ options were not described or discussed.*
- *I've had two different GYNs give me completely contradictory information about the side effects and dangers of BCPs... Overall, I'm surprised at*

*how little doctors seem to know about female BCP- I haven't experienced this amount of ambiguity with any other medical specialty or problem.*

- *I was shocked- and grateful- when I finally found a doctor who discussed alternatives with me, suggested a wide variety of reading, and let me do my own research and make my own decision before wiring[sic] a prescription. After doing the reading, there is no way I will ever take another birth control pill in my life. Every other doctor I had acted like it was giving out Altoids...*
- *I think they're too often the first option doctors prescribe for reasons other than birth control. That's frustrating. They're not a magic pill and some doctors seem to think they are.*
- *No doctor ever talked to me about lots of options for birth control. It was just "you want the Pill? ok, here you go."*

Neutral responses included women voicing their frustration with insurance companies who cover Viagra but not oral contraceptives; women who stopped taking the pill due to increased prescription costs; women who were making suggestions for future research; and other similar responses. One woman said:

*It regulated my menstrual problems well. I didn't expect it, but I felt emotionally happier. Yet my closest friends and family complained that I was acting very strange and depressed. This is why I quite[sic] taking the pill.*

And another :

*I would be interested in learning about the number of women who have had miscarriages and the correlation[sic] with birth control and the length of time birth control was taken. There may be no correlation. But the number of women who have miscarriages is alarming.*

Two other respondents mentioned unplanned pregnancy:



- *I wasn't told herbs can interrupt the pills and I have a Son to prove it.*
- *I was not aware, in 2003, when I loaded up on vitamins and herbal supplements that they could change the effectiveness of the pill... hence, my son!*

The positive responses were often shorter like “Never had a problem” and “very positive experience.” One woman said:

*I've been really happy with the pill I've been on for years and years. I sometimes wonder if it will effect[sic] me having kids or any other negative side effects, but I guess I'll find out later. So far, it's been great and I'm very happy.*

Another replied:

*I think the experience taught me to take responsibility for myself. My dad is the one who actually wanted me to start taking them and even though I was 16, it was a great choice. I am 25 and have never had a pregnancy scare, which is good for me because I am not ready for children right now.*

## **DISCUSSION**

Overall, the results of the survey demonstrated that women do not clearly understand the risks involved with taking birth control pills. Many of them believe that certain risks are only associated with being over 35 years of age and/or smoking. This is not surprising given that only a little over half of the women reported their doctor discussing the risks with them before giving them a prescription. And for a majority of the women, their doctor never discussed other birth control options with them.

Most of the women were asked about their family history before being given a prescription, but fewer than half actually discussed it with their doctor. Almost none of the women reported that their pharmacist discussed the risks with them. And fewer than a

third of the women actually read the risk information that accompanies their prescriptions. The majority of women were not aware of inherited thrombophilia and most are not familiar with the symptoms of blood clots. However, the great majority of women would be willing to take a blood test in order to assess their risk of forming blood clots.

For the most part, these results show what was expected. Most women do not fully understand the risks involved with taking birth control pills, they are not familiar with the symptoms of a blood clot, and they have never heard of clotting disorders. This is perhaps not surprising given the lack of information available to them, as found in the media analysis. The survey results confirm that there is a lack of communication about the risks of taking birth control pills, and virtually no communication about clotting disorders. More importantly, the majority of women who are taking a prescription that increases their risk of blood clots do not even know the symptoms of these preventable conditions.

## **CHAPTER FIVE**

### **INCREASING AWARENESS**

Certainly, the problem of inherited thrombophilia and the increased risks of blood clots when taking OC is a complicated one. There seems to be little consensus in the medical community about how to handle the issue. This investigation has demonstrated that little has been done to inform women of this potentially dangerous interaction. Clearly, most women are unaware of inherited thrombophilia, and therefore unaware of an increased risk when combined with estrogen. Based on my investigation, it appears that the communication breakdown is three fold. Responsibility for such a complex problem lies on the shoulders not only of the prescriber of OC, but also the dispenser of OC, and on the patient. Upon completion of this research it is apparent that there are several ways to improve communication regarding inherited thrombophilia and the dangers of oral contraceptives.

#### **PHARMACEUTICAL MANUFACTURERS RESPONSIBILITY**

Nearly 40% of the women surveyed in this study said they thoroughly read the pharmaceutical insert that accompany their birth control pills, with a further 37% reporting that they at least glance at the materials. If the majority (77%) of women who take birth control pills are at least looking at the information that is provided with their prescriptions, improving this information in content and presentation could increase awareness of blood clots, their symptoms, and inherited thrombophilia. And by doing so, potentially save lives.

Inserts for oral contraceptives should more clearly state that clotting disorders increase the risk of side effects and specify that women may have a clotting disorder despite no prior history or blood clots. Information about testing for these genetic conditions and encouraging women to discuss this with their doctors would also be an improvement. Additionally, the wording that women “should notify your healthcare provider if you notice any unusual physical disturbances while taking the pill” should be changed to a more proactive statement. For example “contact your healthcare professional immediately if you experience any symptoms of a blood clot listed above. If your healthcare provider is unavailable or your symptoms worsen, seek treatment at an emergency healthcare center.” And this information should be included on the small, perforated portion of the insert as well as the main section.

As pointed out by one survey participant, the information in these inserts is “dense” and “not presented in an easy-to-digest format.” Combining poor usability with difficulty people have comprehending abstract statistical information, and deceptive qualifying language practically guarantees a failure to educate women about life threatening risks associated with OC. These inserts need simplified text and statistics that do more than just fulfill legal obligations. They also need to fulfill their obligation to the patient taking the medication to understand her risks.

Dickinson, et al. demonstrated the benefits of consumer testing for medicine leaflets in their 2001 study and found that “leaflets with the appropriate tone, length, and design can do much to aid responsible medicine-taking.” Exhaustive testing is required of pill manufacturers before a medication can be prescribed to the public, but very little, if any, testing is required of the information accompanying these prescriptions. “Studies...

have shown that the wording currently recommended... for conveying risk information is consistently and significantly misinterpreted by users” (Berry 307).

Additionally, pill manufacturers could include the results of both their studies and independent studies in the information provided with the prescription. Since, as Drife points out “studies funded by manufacturers of oral contraceptive pills produce more favorable results than independent studies” (898).

“Framing information in a way that is most readily understood by the human mind is a first step toward educating doctors and patients in risk literacy” (Gigerenzer 58). Women would benefit from pharmaceutical companies updating the information that is distributed with their oral contraceptives to include: more details about clotting disorders, especially that women may have them and not know; simplified text that is targeted to the reader; information that has undergone usability testing for clarity.

As far as the advertising of birth control pills, marketers have an obligation to their clients, the pharmaceutical industries, to make the product appealing. Unfortunately for consumers, this means promoting the benefits while downplaying the side effects. This speaks to the ethics, or lack of ethics, of pharmaceutical advertising. Short of prohibiting all pharmaceutical advertising, it is difficult to say how these advertisements can be improved, and still benefit the companies paying for them. An accurate and fair representation of the medication’s benefits and side effects is the obvious solution. However, both accurate and fair are subjective, especially under the eyes of discriminating legal teams. Nevertheless, the over 10,000% increase in spending on these advertisements, an expense no doubt passed on to millions who rely on these medications, make an appealing case for banishing them.

## **HEALTH CARE PROVIDER/ PATIENT RESPONSIBILITY**

Increasing the awareness of the dangers of thrombophilia combined with OC use involves more than just pharmaceutical company. There are steps that healthcare providers and their patients can take to improve their understanding of the risks of oral contraceptives. If communication can be improved on both sides of the doctor/patient relationship, it is conceivable that clot symptoms will be recognized for the danger that they are and treatment can be administered swiftly.

“Unlike many life-threatening conditions, deep vein thrombosis (DVT) and pulmonary embolism (PE) can strike silently: 80% of DVT and PE occur without symptoms initially. As a result, some clinicians regard DVT and PE as rare” (Church). Unfortunately, blood clots are far from rare. “Venous thromboembolism is a major medical problem, affecting 1 in 1000 individuals annually, and most physicians come in contact with patients suffering from the disease regardless of their clinical specialty” (Dahlback 19). Despite the prevalence of blood clots both healthcare providers and patients continually miss the warning signs.

Fletcher et al. suggest that “preceding OC prescriptions women need to be informed of the potential benefits and risks... healthcare providers should provide users with OC information and periodically review the procedural practices during the duration they consume the pill” (233). Only a little more than half of the women surveyed reported that their doctor discussed the risks of taking birth control pills with them. And more alarmingly, only one woman could accurately identify which risks were actually related to taking OC.

Over 80% of the women surveyed did not know about inherited thrombophilia before taking birth control pills. Women should be systematically informed that it is possible for them to have a clotting disorder without realizing, that is with no prior history of clots and no family history of clots. They should also be given the option to have a blood test to determine whether they are at an increased risk of blood clots when taking oral contraceptives, or in any other increased risk situation (long flights, pregnancy, surgery, bed rest, etc.).

In addition to informing women of the risks associated with oral contraceptive use, healthcare providers need to make sure they emphasize the symptoms of these side effects, especially blood clots. Over 80% of the participants in this study did not know or were not sure they knew the symptoms of blood clot. If a patient cannot identify the symptoms, it is unlikely that they will take appropriate action to seek treatment.

In the Bryden and Fletcher study about the knowledge of university-aged women about the benefits and risks of birth control pills, they mention the acronym ACHES as a list of warning signs. ACHES stand for **A**bdominal pain, **C**hest pain, **H**eadaches, **E**ye/vision changes, **S**evere leg cramps. These are some of the main symptoms of blood clots and according to their study, 69% of the women were able to identify the correct terms for this mnemonic device. It is not known where this acronym originated, but the Bryden and Fletcher study was conducted in Canada. Based on the survey responses in this study, women here in the United States are not familiar ACHES. This device could be a powerful tool for health care providers to help educate patients about the symptoms associated with blood clots.

Healthcare providers also should provide women with an action plan in the event that they experience any side effects- something more substantial than the directive provided with the prescription of “notify your healthcare provider if you notice any unusual physical disturbances.”

Furthermore, even if patients decline the blood test assessing their risk, the very act of offering and declining the test will increase awareness of the side effects of birth control pills. Then these women might more readily recognize the symptoms of a blood clot and seek treatment more quickly. And if informing patients of inherited thrombophilia was standard protocol before prescribing oral contraceptives, healthcare providers would also become more aware of the possibility of blood clots in young women. This increased awareness could result in a quicker response when a patient presents with these symptoms and quite possibly the difference between life and death.

Moreover, physicians need to discuss all contraceptive options with women, even if they request a prescription for birth control pills, as over half the women surveyed did. More than 60% of the participants reported that their doctor’s did not discuss any other options with them. In fact, in the comment section, many women chose to point out how readily their doctors prescribed birth control pills:

- *I think they’re too often the first option doctors prescribe for reasons other than birth control. That’s frustrating. They’re not a magic pill and some doctors seem to think they are.*
- *Doctors are much too quick to prescribe and dismiss the side effects or even give credit to some of the emotional effects I felt the pill caused...*



- *Every other doctor I had acted like it was giving out Altoids, and I always looked at it that way myself as a result- until meeting a new doctor.*

And from one survey participant who chose to send an email after taking the survey:

- *The pill is given out like candy, and women are suffering the results (abnormal paps and cervical cancers scares before age 22 for myself and my sister, long term risks of breast cancer, on and on).*

As far as health care provider and patient responsibility, Edwards et al. point out in a recent article in *Patient Education and Counseling* that risk communication is becoming increasingly more important in the health care. According to the article, risk communication can be defined as “the open two-way exchange of information and opinion about risk, leading to better understanding and better (clinical) decisions” (4). In addition to the healthcare provider’s responsibility to inform patients of risks associated with oral contraceptive use, patients need to take a greater role in their own healthcare.

Edwards et al. also suggest that the healthcare industry is experiencing a shift “from the paternalistic paradigm towards one of greater patient participation and responsibility” (4). With advances in medicine occurring daily, it is impossible for one doctor to have the most up to date information on all conditions and treatments. And in this information age women, especially young women who are seeing doctors for the first time without a parent, need to take responsibility for their own health. It is the responsibility of both the patient and the doctor to ensure the best health care possible is provided.

Obviously this patient/ healthcare provider relationship is an ideal to strive toward. To achieve such an ideal, many communication issues between patients and their

healthcare providers need to be addressed. However, women can take steps to increase their quality of care by researching their complete family medical history, reading all materials that accompany their medication, and keeping abreast of pertinent innovations in medicine.

### **TESTING FOR THROMBOPHILIA**

“In 2001 a consensus statement from the American College of Medical Genetics recommended against screening for factor V Leiden in asymptomatic women contemplating the use of oral contraceptives unless they have a personal or family history of thromboembolism or other risk factors” (Drife 899). The reasoning behind this standard of care is several cost analysis studies that have meticulously broken the argument down into statistics of the cost to prevent one death.

“Although the laboratory cost of screening for factor V Leiden has reduced considerably over the past few years, as screening technology has improved and become more widespread, the cost of seeing patients, obtaining samples from them and subsequently counseling them, means that each patient screened would cost a minimum of £15 and perhaps more realistically £25 at 1999 costs.” (Walker 11). With inflation accounted for at 2% a year, the cost today would be approximately £17 to £30 or \$25 to \$43.

Unfortunately for Americans, according to Greenwood Genetic Center, in Greenwood, South Carolina, a test for factor V Leiden currently costs approximately \$150. The scope of this study does not cover why medical care here in the United States is that much more expensive than in Great Britain. However, the Walker study shows that

it is possible to screen for much less than \$150, and if screening rates were to increase, the cost of the tests would likely decrease. Furthermore, a recent study in Spain has devised a “rapid, reproducible, cost-effective, and simple method... to simultaneously detect carriers of thrombotic genetic risk factors” (Lopez et al. 349). This test removes the manual aspects of the screening process that can increase the cost and the possibility of erroneous test results. And unlike previous automated tests, which can test for only one mutation (i.e. the test from Greenwood Genetic Center that tested only for FVL), this new, inexpensive, and automated test is able to detect multiple mutations in human DNA samples. (Lopez et al. 354).

Only 7% of the women surveyed in this study would *not* be willing to take a blood test to assess their risk for blood clots. And more than 33% of the women surveyed for this study would be willing to pay these costs out of pocket. Moreover, if the test costs were closer to \$20, an additional 30% would be willing to pay. If women are willing to pay for the test, how can it not be cost effective to screen them?

Another thing these “cost effective” analyses fail to take into account is the cost of hospital stays, treatment, and medication for those women who have clots and live, but often need a lifetime of treatment (like myself). Not to mention the huge burden, financial as well as emotional, of the countless miscarriages and stillbirths. Do the lives of unborn babies not count in a cost per preventable death study?

“Of all patient groups evaluated, universal screening of women prior to prescribing hormone replacement therapy was the most cost-effective” (Wu, et al. 131). However, the majority of women that would be screened for hormone replacement therapy have already been on birth control pills or had children, or both. Therefore, if

they had been screened, or at least been given the option to be screened, at the time they were prescribed birth control pills, they would already understand their risk for developing a clot.

Many of these studies propose, in lieu of testing all women, that patients should be screened for a family history and that those with a legacy of blood clots could then be tested. In an article in *Fertility and Sterility*, Dr. Mitchell Crenin and colleagues claim that “the best screening tool we have is taking a thorough personal and family history related to venous thromboembolic events” (650). Though 85% of the women surveyed for this study said they were asked about their family histories, only about half of those actually discussed it with their doctor. And the Fletcher et al. study only found that 61% of women reported receiving a family history review, with 14% unable to recall what information was included in the review (231).

Furthermore, family history has not been proven to be an effective screening tool. In a study published in *Thrombosis and Haemostasis*, Schambeck et al. found that fewer than half of the women with FVL would be discovered if family history were the only basis for screening. They conclude that “many FV Leiden carriers would escape the physician’s notice if one just relies on the family history of the patient” and that “family history is an unreliable criterion to detect FVL carriers” (1480, 1482). Another study by Cosmi et al. concurred, adding “family history of venous thromboembolism has an unsatisfactory sensitivity... a policy of selective screening may therefore miss a substantial number of women at increased risk of thromboembolism when taking oral contraceptives” (1024).

Indeed, my family history shows only a grandmother that had a stroke in her 60s, something easily explained by her age and the fact that she smoked. And one of the survey participants had a similar experience that she described:

*I experienced bilateral pulmonary embolisms when I was taking birth control pills. It turned out that I had factor V Leiden (homozygous), but my family was unaware of our genetic condition until I had my clots. I can't remember my doctor ever discussing blood clot risks with me when prescribing BCPs. My grandfather had had a stroke, but I don't recall discussing that.*

Another researcher recommends testing for FVL only if there is another permanent or short-lasting risk for VTE (Spannagl 111). Other risk factors that should be taken into account are continually being explored. For example, recent studies have shown that migraines, particularly those with auras, or visual disturbances, are a risk factor for stroke, this risk further increased with the use of OC. As previously mentioned, the connection between migraines and strokes is extensive enough that the World Health Organization recommends that women suffering from migraine with aura should never use birth control pills (Allais et al. S12).

A further study by Bassi et al. has shown that 62.5% of patients who suffer migraines carried at least three thrombophilic factors including FVL. Their findings indicate that “in order to assess prevention strategies, it could be appropriate to perform a complete screening in young patients suffering from migraine” (138). It is also my experience that this could be a predictive factor for thrombophilia. Though I have no personal history of migraine, aside from the episode that preceded my stroke, both my sister and mother have long suffered from migraines. In addition, the same survey

participant who reported having pulmonary embolisms as previously quoted, mentioned having a history of migraines:

*I originally took Ortho Tri-cyclen, but the doctor (at the student health clinic) switched me to Mircette to help with migraines. It turns out this is one of the types of BCPs that causes the greatest risk for clots.*

“Paying attention to risk factors has dramatically reduced the incidence of fatal thromboembolism after caesarean section in the UK and the same approach could be applied to thromboembolism and oral contraceptives” (Drife 899). According to the British National Formulary, birth control pills should be avoided if women are obese (Drife 899). However, in the United States, there is no similar restriction, despite ranking as the 9<sup>th</sup> fattest country in the world (Great Britain ranked 28<sup>th</sup>) by the World Health Organization (Streib). Dr. James Trussell explains the danger in *Contraceptive Technology Update*, “While much attention has been focused on OC failure in obese women, clinicians should look at the risk of deep vein thrombosis (DVT) in this population. Obesity is a risk factor for venous thromboembolism, and OCs further increase the effect of obesity on DVTs” (90).

Another concern regarding systematically testing for thrombophilia is that it “may not significantly reduce the incidence of VTE... as the incidence of unplanned pregnancies is likely to increase” (Walker 13). However, just because a woman is advised against taking birth control pills, does not mean she is incapable of using other types of contraception. Intrauterine devices (IUD) and barrier methods are both safe alternatives, and the IUD has been shown to be statistically more effective than most hormonal options (“Facts on Contraceptive Use”). And as Schambeck points out “screening for

FVL can be worthwhile even if the advantages of oral contraception are higher assessed than the thrombotic risk. Affected women knowing about their additional risk could contribute to the prevention of thrombosis in risk situations” (1480).

Perhaps doctors Nina Caplin and Laurie Edelman put it best, in their response in *The New England Journal of Medicine* to an article that suggested women should not be routinely tested for thrombophilia because it “would deny contraceptives to about 5 to 10 percent of white women... while preventing very few fatal thromboembolisms.” They said:

*This is not acceptable. No woman should die unnecessarily from complications of contraceptive use, nor should any woman be subjected to a possible stroke, pulmonary embolism, or deep venous thrombosis when the occurrence of these complications could have possibly been prevented by a simple and accurate blood test. Other acceptable forms of birth control are available. Not offering women an informed choice and thus perhaps significantly increasing their risk of a preventable complication associated with substantial morbidity should not be the standard of care.*

While testing every woman for thrombophilia may still be a debatable practice, this research has shown that most women would be willing to pay for that information about their health. Furthermore, new tests are being created that decrease the cost and error associated with these test. And though she is only one example, the woman surveyed who answered that she knew about clotting disorders because she is “from a family of Drs, so got tested before I began taking the pills,” brings up a good point. If doctors find inherited thrombophilia enough of a risk to test their family members before allowing them to start OC, then every woman should have the right to take the test.

For most health care providers who are reluctant to incorporate thrombophilia testing into their practice, this research provides some illuminating information to consider. Family history is not an accurate tool to identify women with inherited thrombophilias, however a family history of migraines may prove to be an indicator of increased risk of thrombosis. Additionally, clinicians should consider recommending alternative contraceptive options for patients who are obese.



## CHAPTER SIX

### CONCLUSIONS AND LIMITATIONS

Overall this study found that women who use oral contraceptives are not aware of inherited thrombophilia. And like previous research, this study showed that most of those women do not fully understand the risks of taking birth control pills, including their personal risk for blood clots that would be increased if they have a clotting disorder. But perhaps most alarming is that the majority of these women do not even know the symptoms of a blood clot, and would therefore not recognize if they had one, or know to seek treatment immediately.

Additionally, this study confirms the lack of information available to women about clotting disorders. This information is not found in advertisements for birth control pills, on non-profit websites about birth control pills and their risks, or on literature provided with the prescriptions. It should come as no surprise that women are not aware of something so infrequently and inadequately mentioned.

The amount of conflicting information available to women, physicians, and researchers alike, makes it difficult to determine where the breakdown in communication occurs. Clearly, women need more information from their health care providers, however these health care providers need comprehensible and accurate information from pharmaceutical companies. And pharmaceutical companies need take responsibility for making their risk information for birth control pills as easily understandable as their selling points. As mentioned in the results section, many survey participants were dissatisfied with their experience with their healthcare providers. As one woman pointed out:

*I've had two different GYNs give me completely contradictory information about side effects from BCPs... Overall, I'm surprised at how little doctors seem to know about female BCP- I haven't experienced this amount of ambiguity with any other medical specialty or problem.*

This study also made clear that women are eager to have a voice in the on-going dialogue about birth control pills. Even if their issues with oral contraceptive are not related to cardiovascular risks, women still have strong feelings about taking these hormones. Based on the concerns voiced by the women surveyed, it appears that more research should be conducted on birth control pills, their risks, and long and short-term side effects. And this investigation has shown, even more than anticipated, the desperate need for increased awareness of thrombophilia for women.

In spite of this compelling evidence, this study does have limitations. For example, because the survey participants were recruited online through networking, it is possible that some may have been aware of my experience and therefore were biased in their responses. This was countered by qualifying the question about knowledge of clotting disorders with the option of knowing about clotting disorders but not being aware of them when they first began taking OC. Ideally, participants with no prior knowledge of the researcher would be have been randomly selected for the survey. However, time constraints required this study to be conducted with the convenience sample available.

Also, to provide the most anonymity possible for participants, they were not requested to provide information on their educational background, race, or socioeconomic status. This limits the demographic information available. Because the survey was conducted online, all respondents had to have access to a computer and email

or Facebook. It is therefore reasonable to conclude that participants were fairly educated and reasonably well-off.

This study was also limited by a lack of published research on this topic in the United States. The majority of the articles cited in this thesis were studies done in Europe or Canada. Though it is unlikely that results for most of these studies would be different had they been conducted in the United States, it cannot be concluded that all of the information can be transferred. It is unfortunate and disconcerting that comparable studies done in United States could not be found. But perhaps this is not surprising given that by 1988 surveys showed “that birth control has disappeared from the list of medical research's 35 top priorities” (“Timeline: The Pill”).

That said, the object of this study was not to vilify oral contraceptives or to deny them to any woman looking for effective means of contraception. Certainly oral contraceptives are of considerable benefit to many woman in the United States and perhaps even more so in developing countries, where the risk of maternal death is much greater than the risks involved with taking oral contraceptives

However, the benefits of oral contraceptives do not always outweigh the risks, particularly in women with clotting disorders. Now that more accurate and cost effective tests for clotting disorders have been identified, testing should be considered especially in women who have additional risk factors that have been identified. Additionally, since this research shows that most women would be willing to take the test, and even pay for it, testing should be made available to them, as well as information about clotting disorders.

While there will always be extraordinary situations, with the amount of existing knowledge and technology, there is no excuse for women to suffer strokes, pulmonary

embolisms, DVTs, multiple miscarriages, and still births because they have an undiagnosed clotting disorder. As the Surgeon General pointed out, blood clots are preventable. By making women aware of inherited thrombophilia, the risks involved with taking hormones, and the symptoms of thrombosis, we can reduce the instance and severity of life threatening conditions.

## CHAPTER SEVEN

### EPILOGUE

After I got out of the hospital, I was referred to a hematologist who diagnosed me with Factor V Leiden. When my test came back as “only” heterozygous, he treated my situation like it was, for lack of a better phrase, no big deal. This left me frustrated and confused. If my clotting disorder was no big deal, then why did it nearly kill me?

I wanted to know why no one had ever told me about the existence- or my chance of ever having- clotting disorders. I wanted to know why doctors had prescribed me birth control pills without informing me about the side effects or offering me any other options. I wanted to know why when I researched my symptoms online, the only information I could find indicated that I had a migraine. And most importantly, I wanted to know why over the course of a week, four physicians, including an OB-GYN, a physician at an urgent care clinic, and two different emergency room doctors, did not even consider that I might have a blood clot, despite being on birth control pills and presenting with symptoms of a stroke- and in the case of the OB-GYN office, a DVT (an unexplainable pain in my thigh).

These questions were the impetus for this research study. Obviously my bias has formed this work, perhaps in ways that I cannot even realize. But my passion for the subject also motivated me to keep researching when many articles concluded that FVL was not prevalent enough or dangerous enough to warrant testing. While the scope of this research does not cover all of the issues that accompany systematic testing of women prior to prescribing birth control pills, I believe it demonstrates that a simple cost-per-death-prevented ratio does not adequately address this issue. And unlike other research

on FVL, this study incorporates a point of view that is so often missing in a much of medical research: that of the patient.

Not long after I was discharged from the hospital, I had an allergic reaction to my anti-seizure medicine. I returned to the emergency room at the request of my neurologist. This time they immediately took me to an examination room. When the doctor walked in, the same doctor who had finally diagnosed my stroke, he impressed upon me the gravity of my situation and of this issue when he said to me, “I’m so glad to see you. I didn’t think you were going to make it.”

## APPENDICES

# APPENDIX A

## BACK PAGES OF ADVERTISEMENTS

Yaz

### BRIEF SUMMARY PATIENT PACKAGE INSERT

#### YAZ®

(drospirenone and ethinyl estradiol) Tablets  
containing the following:  
24 light pink "active" tablets  
4 white "inert" tablets

This product (like all oral contraceptives) is intended to prevent pregnancy. It does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

YAZ® is different from other birth control pills because it contains the progestin drospirenone. Drospirenone may increase potassium. Therefore, you should not take YAZ if you have kidney, liver or adrenal disease because this could cause serious heart and health problems. Other drugs may also increase potassium. If you are currently on daily, long-term treatment for a chronic condition with any of the medications below, you should consult your healthcare provider about whether YAZ is right for you, and during the first month that you take YAZ, you should have a blood test to check your potassium level.

- NSAIDs (ibuprofen [Motrin, Advil], naproxen [Aleve and others] when taken long-term and daily for treatment of arthritis or other problems)
- Potassium-sparing diuretics (spironolactone and others)
- Potassium supplementation
- ACE inhibitors (Capoten, Vasotec, Zestril and others)
- Angiotensin-II receptor antagonists (Cazarr, Diovan, Avapro and others)
- Heparin
- Aldosterone antagonists

#### INDICATIONS

1. YAZ is indicated for the prevention of pregnancy in women who elect to use an oral contraceptive.
2. YAZ is also indicated for the treatment of symptoms of premenstrual dysphoric disorder (PMDD) in women who choose to use an oral contraceptive as their method of contraception. The effectiveness of YAZ for PMDD when used for more than three menstrual cycles has not been evaluated.
3. YAZ is indicated for the treatment of moderate acne vulgaris in women at least 14 years of age, who have no known contraindications to oral contraceptive therapy and have achieved menarche. YAZ should be used for the treatment of acne only if the patient desires an oral contraceptive for birth control.

YAZ is an oral contraceptive, also known as a "birth control pill" or "the Pill." Oral contraceptives are taken to prevent pregnancy, and, when taken correctly without missing any pills, have a failure rate of approximately 1% per year (1 pregnancy per 100 women per year of use). The typical failure rate in pill users is approximately 5% per year (5 pregnancies per 100 women per year of use) when women who miss pills are included. Forgetting to take pills consistently increases the chances of pregnancy.

YAZ may also be taken to treat premenstrual dysphoric disorder (PMDD) if you choose to use the Pill for birth control. Unless you have already decided to use the Pill for birth control, you should not start YAZ to treat your PMDD because there are other medical therapies for PMDD that do not have the same risks as the Pill. PMDD is a mood disorder related to the menstrual cycle. PMDD significantly interferes with work or school, or with usual social activities and relationships with others. Symptoms include markedly depressed mood, anxiety or tension, mood swings, and persistent anger or irritability. Other features include decreased interest in usual activities, difficulty concentrating, lack of energy, change in appetite or sleep, and feeling out of control. Physical symptoms associated with PMDD may include breast tenderness, headache, joint and muscle pain, bloating and weight gain. These symptoms occur regularly before menstruation starts and go away within a few days following the start of the period. Diagnosis of PMDD should be made by healthcare providers.

You should only use YAZ for treatment of PMDD if you:

- Have already decided to use oral contraceptives for birth control, and
- Have been diagnosed with PMDD by your healthcare provider.

YAZ has not been shown to be effective for the treatment of premenstrual syndrome (PMS), a less serious cluster of symptoms occurring before menstruation. If you or your healthcare provider believes you have PMS, you should only take YAZ if you want to prevent pregnancy, and not for the treatment of PMS.

YAZ may also be taken to treat moderate acne in women who are able to and wish to use the pill for birth control.

Any woman who needs contraception (birth control) and chooses to use an oral contraceptive should understand the benefits and risks of using the Pill. This leaflet will give you much of the information you will need to help you decide if you should use the Pill for contraception and will also help you determine if you are at risk of developing any of the serious side effects of the Pill. It will tell you how to use the Pill properly so that it will be as effective as possible. However, this leaflet is not a replacement for a careful discussion between you and your healthcare professional. You should discuss the information provided in this leaflet with him or her, both when you first start taking the Pill and during your visits. You should also follow your healthcare professional's advice with regard to regular check-ups while you are on the Pill.

For the majority of women, oral contraceptives can be taken safely. But there are some women who are at high risk of developing certain serious diseases that can be life-threatening or may cause temporary or permanent disability or death. The risks associated with taking oral contraceptives increase significantly if you:

- smoke
- have high blood pressure, diabetes, high cholesterol, or are obese
- have or have had clotting disorders, heart attack, stroke, angina pectoris (severe chest pain), cancer of the breast or sex organs, jaundice, or malignant or benign liver tumors.

You should not take the pill if you suspect you are pregnant or have unexplained vaginal bleeding.

Although cardiovascular disease risks may be increased with oral contraceptive use after age 40 in healthy, non-smoking women (even with the newer low-dose formulations), there are also greater potential health risks associated with pregnancy in older women.

Cigarette smoking increases the risk of serious adverse effects on the heart and blood vessels from oral contraceptives. This risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use oral contraceptives should not smoke.

Most side effects of the pill are not serious. The most common such effects are nausea, vomiting, bleeding between menstrual periods, weight gain, breast tenderness, and difficulty wearing contact lenses. These side effects, especially nausea and vomiting may subside within the first three months of use.

The serious side effects of the pill occur very infrequently, especially if you are in good health and are young. However, you should know that the following medical conditions have been associated with or made worse by the pill:

1. Blood clots in the legs (thrombophlebitis), lungs (pulmonary embolism), blockage or rupture of a blood vessel in the brain (stroke), blockage of blood vessels in the heart (heart attack and angina pectoris) or other organs of the body. As mentioned above, smoking increases the risk of heart attacks and strokes and subsequent or fatal medical consequences. Women with migraine headaches also may be at increased risk of stroke when taking the pill.
2. Liver tumors, which may rupture and cause severe bleeding. A possible but not definite association has been found with the pill and liver cancer. However, liver cancers are an extremely rare. The chance of developing liver cancer from using the pill is thus even rarer.
3. High blood pressure, although blood pressure usually returns to normal when the pill is stopped.
4. Cancer of the breast. Various studies give conflicting reports on the relationship between breast cancer and oral contraceptive use. Oral contraceptive use may slightly increase your chance of having breast cancer diagnosed, particularly after using hormonal contraceptives at a younger age. After you stop using hormonal contraceptives, the chances of getting breast cancer begin to go back down. You should have regular breast examinations by a healthcare provider and examine your own breasts monthly. Tell your healthcare provider if you have a family history of breast cancer or if you have had breast nodules or an abnormal mammogram. Women who currently have or have had breast cancer should not use oral contraceptives because breast cancer is a hormone-sensitive tumor.

Some studies have found an increase in the incidence of cancer or precancerous lesions of the cervix in women who use the pill. However, this finding may be related to factors other than the use of the pill.

The symptoms associated with these serious side effects are discussed in the detailed leaflet given to you with your supply of pills. Notify your doctor or healthcare provider if you notice any unusual physical disturbances while taking the pill. In addition, drugs such as rifampin, as well as some anticancerous, some antibiotics and some herbal products such as St. John's Wort, may decrease oral contraceptive effectiveness.

Taking the pill may provide some important non-contraceptive benefits. These include less pain with menstruation, less menstrual blood loss and anemia, fewer pelvic infections, and fewer cancers of the ovary and the lining of the uterus. Be sure to discuss any medical condition you may have with your healthcare provider. Your healthcare provider will take a medical and family history before prescribing oral contraceptives and will examine you. The physical examination may be delayed to another time if you request it and the healthcare provider believes that it is appropriate to postpone it. You should be reexamined at least once a year while taking oral contraceptives. The detailed patient information booklet gives you further information which you should read and discuss with your healthcare provider.

This product (like all oral contraceptives) is intended to prevent pregnancy. Oral contraceptives do not protect against HIV infection (AIDS) and other sexually transmitted diseases such as chlamydia, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis.

#### INSTRUCTIONS TO PATIENTS

##### HOW TO TAKE THE PILL

##### IMPORTANT POINTS TO REMEMBER

##### BEFORE YOU START TAKING YOUR PILLS:

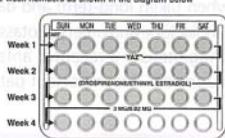
1. BE SURE TO READ THESE DIRECTIONS: Before you start taking your pills. Anytime you are not sure what to do.
2. THE RIGHT WAY TO TAKE THE PILL IS TO TAKE ONE PILL EVERY DAY AT THE SAME TIME. YAZ CAN BE TAKEN WITHOUT REGARD TO MEALS. If you miss pills you could get pregnant. This includes starting the pack late. The more pills you miss, the more likely you are to get pregnant. See "WHAT TO DO IF YOU MISS PILLS" below.
3. MANY WOMEN HAVE SPOTTING OR LIGHT BLEEDING, OR MAY FEEL SICK TO THEIR STOMACH DURING THE FIRST 1-3 PACKS OF PILLS. If you do have spotting or light bleeding or feel sick to your stomach, do not stop taking the pill. The problem will usually go away. If it does not go away, check with your healthcare provider.
4. MISSING PILLS CAN ALSO CAUSE SPOTTING OR LIGHT BLEEDING, even when you make up these missed pills. On the days you take two pills, to make up for missed pills, you could also feel a little sick to your stomach.
5. IF YOU HAVE VOMITING (within 3 to 4 hours after you take your pill), you should follow the instructions for "WHAT TO DO IF YOU MISS PILLS." IF YOU HAVE DIARRHEA, or IF YOU TAKE CERTAIN MEDICINES, including some antibiotics and some herbal products such as St. John's Wort, your pills may not work as well. Use a back-up method (such as condoms or spermicides) until you check with your healthcare provider.
6. IF YOU HAVE TROUBLE REMEMBERING TO TAKE THE PILL, talk to your healthcare provider about how to make pill-taking easier or about using another method of birth control.
7. IF YOU HAVE ANY QUESTIONS OR ARE UNSURE ABOUT THE INFORMATION IN THIS LEAFLET, call your healthcare provider.

##### BEFORE YOU START TAKING YOUR PILLS

1. DECIDE WHAT TIME OF DAY YOU WANT TO TAKE YOUR PILL. It is important to take YAZ at about the same time every day. YAZ can be taken without regard to meals.
2. LOOK AT YOUR PILL PACK - IT HAS 28 PILLS. The YAZ pill pack has 24 light pink "active" pills (with hormones) to be taken for 24 days, followed by 4 white "reminder" pills (without hormones) to be taken for four days.

##### 3. ALSO FIND:

- 1) Where on the pack to start taking pills.
- 2) In what order to take the pills (follow the arrows)
- 3) The week numbers as shown in the diagram below



#### 4. BE SURE YOU HAVE READY AT ALL TIMES:

ANOTHER KIND OF BIRTH CONTROL (such as condoms or spermicides) to use as a back-up in case you miss pills.

#### AN EXTRA FULL PILL PACK.

#### WHEN TO START THE FIRST PACK OF PILLS

You have a choice for which day to start taking your first pack of pills. Decide with your healthcare provider which is the best day for you. Pick a time of day which will be easy to remember.

#### DAY 1 START:

1. Take the first light pink "active" pill of the first pack during the first 24 hours of your period.
2. You will not need to use a back-up method of birth control, since you are starting the pill at the beginning of your period.

#### SUNDAY START:

1. Take the first light pink "active" pill of the first pack on the Sunday after your period starts, even if you are still bleeding. If your period begins on Sunday, start the pack that same day.
2. Use another method of birth control (such as condoms or spermicides) as a back-up method if you have sex anytime from the Sunday you start your first pack until the next Sunday (7 days).

#### WHEN YOU SWITCH FROM A DIFFERENT BIRTH CONTROL PILL

When switching from another birth control pill, YAZ should be started on the same day that a new pack of the previous birth control pills would have been started.

#### WHAT TO DO DURING THE MONTH

1. TAKE ONE PILL AT THE SAME TIME EVERY DAY UNTIL THE PACK IS EMPTY. Do not skip pills even if you are spotting or bleeding between monthly periods or feel sick to your stomach (nausea). Do not skip pills even if you do not have sex very often.
2. WHEN YOU FINISH A PACK OF PILLS. Start the next pack on the day after your last white "reminder" pill. Do not wait any days between packs.

#### WHAT TO DO IF YOU MISS PILLS

If you MISS 1 light pink "active" pill in Week 1 of your pack:

1. Take it as soon as you remember. Take the next pill at your regular time. This means you may take two pills in one day.
2. You do not need to use a back-up birth control method if you have sex.

If you MISS 2 light pink "active" pills in a row in WEEK 1 or WEEK 2 of your pack:

1. Take two pills on the day you remember and two pills the next day.
2. Then take one pill a day until you finish the pack.

If you MISS 3 or MORE light pink "active" pills in a row during ANY WEEK:

1. If you are a Day 1 Starter: THROW OUT the rest of the pill pack and start a new pack that same day. If you are a Sunday Starter: Keep taking one pill every day until Sunday. On Sunday, THROW OUT the rest of the pack and start a new pack of pills that same day.
2. You COULD BECOME PREGNANT if you have sex in the 7 days after you restart your pills. You MUST use another birth control method (such as condoms or spermicides) as a back-up for those 7 days.
3. You may not have your period this month but this is expected. However, if you miss your period two months in a row, call your healthcare provider because you might be pregnant.

If you MISS 3 OR MORE light pink "active" pills in a row during ANY WEEK:

1. If you are a Day 1 Starter: THROW OUT the rest of the pill pack and start a new pack that same day. If you are a Sunday Starter: Keep taking 1 pill every day until Sunday. On Sunday, THROW OUT the rest of the pack and start a new pack of pills that same day.
2. You COULD BECOME PREGNANT if you have sex in the 7 days after you restart pills. You MUST use another birth control method (such as condoms or spermicides) as a back-up for those 7 days.
3. You may not have your period this month but this is expected. However, if you miss your period two months in a row, call your healthcare provider because you might be pregnant.

If you MISS ANY of the 4 white "reminder" pills in Week 4:

1. THROW AWAY the pills you missed. Keep taking one pill each day until the pack is empty. You do not need a back-up method of birth control.

FINALLY, IF YOU ARE STILL NOT SURE WHAT TO DO ABOUT THE PILLS YOU HAVE MISSED:

1. Use a BACK-UP METHOD (such as condoms or spermicides) anytime you have sex.
2. KEEP TAKING ONE ACTIVE LIGHT PINK PILL EACH DAY until you can contact your healthcare provider.

For additional information see "Detailed Patient Labeling"

Manufactured by:  
**Bayer HealthCare**  
Pharmaceuticals  
Bayer HealthCare Pharmaceuticals Inc.  
Wayne, NJ 07470  
Manufactured in Germany

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Printed in U.S.A. 6061602BH October 2007



LYBREL™ (90 mcg levonorgestrel and 20 mcg ethinyl estradiol) Tablets  
For full Prescribing Information and Detailed Patient Labeling, please visit [www.lybrel.com](http://www.lybrel.com).

**Brief Summary Patient Package Insert**

**This product (like all oral contraceptives) is intended to prevent pregnancy. Oral contraceptives do not protect against transmission of HIV (AIDS) and other sexually transmitted diseases (STDs) such as chlamydia, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis.**

Oral contraceptives, also known as "birth-control pills" or "the pill," are taken to prevent pregnancy, and when taken correctly, have a failure rate of approximately 1-2% per year (1 to 2 pregnancies per 100 women per year of use) when used without missing any pills. The average failure rate of large numbers of pill users is approximately 5% per year (5 pregnancies per 100 women per year of use) when women who miss pills are included. However, forgetting to take pills considerably increases the chances of pregnancy. Lybrel is a birth-control pill that is taken every day. When you take Lybrel, the lining of your uterus does not undergo the changes needed for menstruation, and therefore you do not have regular menstrual periods. You are likely to have unscheduled or unplanned bleeding or spotting when you start to use Lybrel. The number of days each month with unscheduled bleeding and spotting usually decreases over time for the majority of women. When using Lybrel, the convenience of having no regular menstrual periods should be weighed against the inconvenience of unscheduled or unplanned breakthrough bleeding and spotting.

For the majority of women, oral contraceptives can be taken safely. However, there are some women who are at high risk of developing certain serious diseases that can be life-threatening or may cause temporary or permanent disability or death. The risks associated with taking oral contraceptives increase significantly if you:

- smoke
- have high blood pressure, diabetes, high cholesterol, or a tendency to form blood clots, or are obese
- have or have had clotting disorders, heart attack, stroke, angina pectoris, cancer of the breast or sex organs, jaundice, malignant or benign liver tumors, or major surgery with prolonged immobilization
- have headaches with neurological symptoms

You should not take the pill if you suspect you are pregnant or have unexplained vaginal bleeding.

Although cardiovascular disease risks may be increased with oral contraceptive use in healthy, non-smoking women over 40 (even with the newer low-dose formulations), there are also greater potential health risks associated with pregnancy in older women.

**Cigarette smoking increases the risk of serious adverse effects on the heart and blood vessels from oral contraceptive use. This risk increases with age and with the amount of smoking (15 or more cigarettes per day has been associated with a significantly increased risk) and is quite marked in women over 35 years of age. Women who use oral contraceptives should not smoke.**

Most side effects of the pill are not serious. The most common such effects are nausea, vomiting, unscheduled bleeding, weight gain, breast tenderness, and difficulty wearing contact lenses. These side effects, especially nausea and vomiting, may subside within the first three months of use.

The serious side effects of the pill occur very infrequently, especially if you are in good health and do not smoke. However, you should know that the following medical conditions have been associated with or made worse by the pill:

1. Blood clots in the legs (thrombophlebitis), lungs (pulmonary embolism), stoppage or rupture of a blood vessel in the brain (stroke), blockage of blood vessels in the heart (heart attack and angina pectoris) or other organs of the body. As mentioned above, smoking increases the risk of heart attacks and strokes and subsequent serious medical consequences. Women with migraine also may be at increased risk of stroke with pill use.
2. Liver tumors, which may rupture and cause severe bleeding. A possible, but not definite, association has been found with the pill and liver cancer. However, liver cancers are extremely rare. The chance of developing liver cancer from using the pill is thus even rarer.
3. High blood pressure, although blood pressure usually returns to normal when the pill is stopped.

The symptoms associated with these serious side effects are discussed in the detailed leaflet given to you with your supply of pills. Notify your health care provider if you notice any unusual physical disturbances while taking the pill. In addition, drugs such as rifampin, as well as some anticonvulsants and some antibiotics, herbal preparations containing St. John's Wort (*Hypericum perforatum*), and HIV/AIDS drugs may decrease oral contraceptive effectiveness.

Various studies give conflicting reports on the relationship between breast cancer and oral contraceptive use.

Oral contraceptive use may slightly increase your chance of having breast cancer diagnosed, particularly if you started using hormonal contraceptives at a younger age.

After you stop using hormonal contraceptives, the chances of having breast cancer diagnosed begin to go down, and disappear 10 years after stopping use of the pill. It is not known whether this slightly increased risk of having breast cancer diagnosed is caused by the pill. It may be that women taking the pill were examined more often, so that breast cancer was more likely to be detected. You should have regular breast examinations by a health care professional and examine your own breasts monthly. Tell your health care professional if you have a family history of breast cancer or if you have had breast nodules or an abnormal mammogram. Women who currently have or have had breast cancer should not use oral contraceptives because breast cancer is usually a hormone-sensitive tumor.

Some studies have found an increase in the incidence of cancer of the cervix in women who use oral contraceptives. However, this finding may be related to factors other than the use of oral contraceptives.

Taking the pill provides some important noncontraceptive benefits. These include less painful menstruation, fewer pelvic infections, and fewer cancers of the ovary and the lining of the uterus.

Be sure to discuss any medical condition you may have with your health care provider. Your health care provider will take a medical and family history before prescribing oral contraceptives and will examine you. The physical examination may be delayed to another time if you request it, and the health care provider believes that it is appropriate to postpone it. You should be reexamined at least once a year while taking oral contraceptives. The detailed patient information leaflet gives you further information which you should read and discuss with your health care provider.

**What You Should Know About Your Menstrual Cycle When You Use Lybrel**

You are likely to have unscheduled or unplanned bleeding or spotting when you start to use Lybrel. The number of days each month with bleeding or spotting usually decreases over time in the majority of women. In a study of Lybrel, about 5 out of 10 women had 7 or more days of bleeding or spotting while using their third 28-day pill pack of Lybrel. The number of women with 7 or more days of bleeding or spotting decreased to 3 out of 10 women during the use of their seventh pill pack. Among women who continued to use Lybrel for one year, about 6 out of 10 women had no bleeding or spotting during their last month of use. Do not stop taking Lybrel because of bleeding or spotting as this will increase your chance of getting pregnant. If the spotting or bleeding continues for more than 7 consecutive days or if the bleeding is heavy, call your health care provider.

**Can I Get Pregnant While Taking Lybrel?**

You are not likely to get pregnant if you take Lybrel at the same time everyday as directed by your health care provider. Because regular monthly bleeding does not occur on Lybrel, it may be difficult to recognize if you get pregnant. If you suspect that you may be pregnant, or if you have symptoms of pregnancy such as nausea/vomiting or unusual breast tenderness, you should have a pregnancy test and you should contact your health care professional. Stop taking Lybrel if you are pregnant.

**PREGNANCY AFTER STOPPING THE PILL**

If you do not desire pregnancy, you should use another method of birth control immediately after stopping Lybrel. You can get pregnant within days after stopping Lybrel.

For information on HOW TO TAKE Lybrel, including Important Points to Remember and WHAT TO DO IF YOU MISS PILLS, please see the Detailed Patient Labeling for Lybrel.

This product's label may have been updated. For current package insert and further product information, please visit [www.wyeth.com](http://www.wyeth.com) or call our medical communications department toll-free at 1-800-934-5556.

Wyeth Pharmaceuticals Inc.  
Philadelphia, PA 19101

This Brief Summary is based on LYBREL (90 mcg levonorgestrel and 20 mcg ethinyl estradiol) Tablets Prescribing Information.

W10523P002  
ET02  
Revised 05/07  
216181-01

**Wyeth®**

© 2007, Wyeth Pharmaceuticals Inc., Philadelphia, PA 19101

## Loestrin24 Fe

### Loestrin® 24 Fe

(norethindrone acetate and ethinyl estradiol tablets, USP and ferrous fumarate tablets)  
Ferrous fumarate tablets are not USP for dissolution and assay.

#### BRIEF SUMMARY OF PATIENT INFORMATION

**This product (like all oral contraceptives) is intended to prevent pregnancy. It does not protect against HIV infection (AIDS) and other sexually transmitted diseases.**

Oral contraceptives, also known as "birth control pills" or "the pill," are taken to prevent pregnancy, and when taken correctly without missing any pills, have a failure rate of about 1% per year (1 pregnancy per 100 women per year of use). The typical failure rate of pill users is 5% (5 pregnancies per 100 women per year of use) when women who miss pills are included.

For the majority of women, oral contraceptives can be taken safely. But for some women oral contraceptive use is associated with certain serious medical problems that can be life-threatening or may cause temporary or permanent disability or death. The risks associated with taking oral contraceptives increase significantly if you:

- Smoke
- Have high blood pressure, diabetes, high cholesterol, or are obese
- Have or have had clotting disorders, heart attack, stroke, angina pectoris (severe chest pains), cancer of the breast or sex organs, jaundice, or malignant or benign liver tumors

You should not take the pill if you are pregnant or have unexplained vaginal bleeding.

Although cardiovascular disease risks may be increased with oral contraceptive use after age 40 in healthy, non-smoking women (even with the newer low-dose formulations), there are also greater potential health risks associated with pregnancy in older women.

**Cigarette smoking increases the risk of serious adverse effects on the heart and blood vessels from oral contraceptive use. This risk increases with age and with the amount of smoking (15 or more cigarettes per day has been associated with a significantly increased risk) and is quite marked in women over 35 years of age. Women who use oral contraceptives should not smoke.**

Most side effects of the pill are not serious. The most common are nausea, vomiting, bleeding or spotting between menstrual periods, weight gain, breast tenderness, and difficulty wearing contact lenses. These side effects, especially nausea and vomiting, may decrease or subside within the first three months of use.

The serious side effects of the pill occur very infrequently, especially if you are in good health and do not smoke. However, you should know that the following medical conditions have been associated with or made worse by the pill:

1. Blood clots in the legs (thrombophlebitis), lungs (pulmonary embolism), stoppage or rupture of a blood vessel in the brain (stroke), blockage of blood vessels in the heart (heart attack or angina pectoris), or other organs of the body. As mentioned above, smoking increases the risk of heart attacks and strokes and subsequent serious medical consequences. Women with migraine headaches also may be at increased risk of stroke when taking the pill.
2. Liver tumors, which may rupture and cause severe bleeding. A possible but not definite association has been found with the pill and liver cancer. However, liver cancers are extremely rare. The chance of developing liver cancer from using the pill is thus even rarer.
3. High blood pressure, although blood pressure usually returns to normal when the pill is stopped.

The symptoms associated with these serious side effects are discussed in the **DETAILED PATIENT INFORMATION** leaflet given to you with your supply of pills. Notify your healthcare provider if you notice any unusual physical disturbances while taking the pill. In addition, drugs such as rifampin, as well as some anticonvulsants and some antibiotics, and herbal preparations containing St. John's Wort (*hypericum perforatum*), may decrease oral contraceptive effectiveness.

Breast cancer has been diagnosed slightly more often in women who use the pill than in women of the same age who do not use the pill. This very small increase in the number of breast cancer diagnoses gradually disappears during the 10 years after stopping use of the pill. It is not known whether the difference is caused by the pill. It may be that women taking the pill are examined more often, so that breast cancer is more likely to be detected. You should have regular breast examinations by a healthcare provider and examine your own breasts monthly. Tell your healthcare provider if you have a family history of breast cancer or if you have had breast nodules or an abnormal mammogram. Women who currently have or have had breast cancer should not use hormonal contraceptives because breast cancer is usually a hormone-sensitive tumor.

Some studies have found an increase in the incidence of cancer or precancerous lesions of the cervix in women who use the pill. However, this finding may be related to factors other than the use of the pill.

Taking the combination pill provides some important noncontraceptive health benefits. These include less painful menstruation, less menstrual blood loss and anemia, fewer pelvic infections, and fewer cancers of the ovary and the lining of the uterus.

Be sure to discuss any medical condition you may have with your healthcare provider. Your healthcare provider will take a medical and family history before prescribing oral contraceptives and will examine you. The physical examination may be delayed to another time if you request it and the healthcare provider believes that it is a good medical practice to postpone it. You should be reexamined at least once a year while taking oral contraceptives. The detailed patient information leaflet gives you further information which you should read and discuss with your healthcare provider.

Manufactured by: Warner Chilcott Company, Inc., Fajardo, PR 00738

Marketed by: Warner Chilcott (US), Inc., Rockaway, NJ 07866



0530G140 Revised November 2006







APPENDIX C  
IRB CONSENT AND APPROVAL

**Consent Form for Participation in a Research Study  
Clemson University**

***Birth Control Pill Survey***

**Description of the research and your participation**

You are invited to participate in a research study conducted by Kerry Gomer, under the direction of Dr. Sean Williams. The purpose of this research is to understand more about birth control pills.

Your participation will involve taking an online survey.  
The amount of time required for your participation will be 5-10 minutes.

**Risks and discomforts**

There are no known risks associated with this research.

**Potential benefits**

There are no known benefits to you that would result from your participation in this research. This research may help us to understand how women obtain information about birth control pills.

**Protection of confidentiality**

Participants taking this survey will remain anonymous.

In rare cases, a research study will be evaluated by an oversight agency, such as the Clemson University Institutional Review Board or the federal Office for Human Research Protections, that would require that we share the information we collect from you. If this happens, the information would only be used to determine if we conducted this study properly and adequately protected your rights as a participant.

**Voluntary participation**

Your participation in this research study is voluntary. You may choose not to participate and you may withdraw your consent to participate at any time. You will not be penalized in any way should you decide not to participate or to withdraw from this study.

**Contact information**

If you have any questions or concerns about this study or if any problems arise, please contact Dr. Sean Williams at Clemson University at 864-656-2156. If you have any questions or concerns about your rights as a research participant, please contact the Clemson University Institutional Review Board at 864.656.6460

**From:** Rebecca Alley  
**Sent:** Thursday, February 05, 2009 9:41 AM  
**To:** Sean Williams  
**Subject:** Validation of IRB protocol # IRB2009-031, entitled "Birth Control Pills: Communicating the Risks"

Dear Dr. Williams,

The Chair of the Clemson University Institutional Review Board (IRB) validated the protocol identified above using Exempt review procedures and a determination was made on **February 5, 2009**, that the proposed activities involving human participants qualify as Exempt from continuing review under **Category B2**, based on the Federal Regulations (45 CFR 46). You may begin this study.

Please remember that no change in this research protocol can be initiated without prior review by the IRB. Any unanticipated problems involving risks to subjects, complications, and/or any adverse events must be reported to the Office of Research Compliance (ORC) immediately. You are requested to notify the ORC when your study is completed or terminated.

Attached are documents developed by Clemson University regarding the responsibilities of Principal Investigators and Research Team Members. Please be sure these are distributed to all appropriate parties.

Good luck with your study and please feel free to contact us if you have any questions. Please use the IRB number and title in all communications regarding this study.

Sincerely,

*Rebecca L. Alley, J.D.*

IRB Coordinator

Office of Research Compliance

Clemson University

223 Brackett Hall

Clemson, SC 29634-5704

Office Phone: 864-656-0636

APPENDIX D  
BIRTH CONTROL PILL SURVEY

**Birth Control Pill Survey**

**1. Survey Information**

If you are over 18 years of age and have ever taken birth control pills, you are invited to participate in this research study conducted by Kerry Gomer, under the direction of Dr. Sean Williams. The purpose of this research is to understand more about birth control pill use.

Your participation will involve taking an online survey.

The amount of time required for your participation will be 5-10 minutes.

There are no known risks associated with this research.

There are no known benefits to you that would result from your participation in this research. This research may help us to understand how women obtain information about birth control pills.

Participants taking this survey will remain anonymous.

Your participation in this research study is voluntary. You may choose not to participate and you may withdraw your consent to participate at any time. You will not be penalized in any way should you decide not to participate or to withdraw from this study.

In rare cases, a research study will be evaluated by an oversight agency, such as the Clemson University Institutional Review Board or the federal Office for Human Research Protections, that would require that we share the information we collect from you. If this happens, the information would only be used to determine if we conducted this study properly and adequately protected your rights as a participant.

If you have any questions or concerns about this study or if any problems arise, please contact Dr. Sean Williams at Clemson University at 864-656-2156. If you have any questions or concerns about your rights as a research participant, please contact the Clemson University Institutional Review Board at 864.656.6460.



## Birth Control Pill Survey

### 2. Birth Control Pill Survey

**1. How old were you when you first started taking birth control pills?**

**2. In (approximately) what year did you first take birth control pills?**

**3. In what year did you stop taking birth control pills? (skip question if currently taking birth control pills)**

**4. Where were you first prescribed birth control pills?**

- OB-GYN office
- Student Health Center (college campus)
- Family Doctor/ General Practitioner office
- Planned Parenthood
- Other (please specify)

**5. What is the main reason you were you first prescribed birth control pills?**

- I asked for a prescription for birth control pills.
- I wanted birth control and pills were recommended by my health care provider.
- My doctor prescribed birth control pills for purposes other than birth control (regulate periods, taking Acutane, etc).
- Other (please specify)

**6. Did your health care provider discuss any other birth control options with you prior to prescribing the pill?**

- Yes
- No
- Other (please specify)

## Birth Control Pill Survey

### 3. Risks

**1. Prior to being prescribed birth control pills, were you asked about your family's medical history?**

- Yes  
 No

**2. If yes, how were you asked about your family medical history?**

- I filled it out on a form.  
 I filled it out on a form and my health care provider discussed it with me.  
 Other (please specify)

**3. The following are a list of health risks, please indicate which ones you think are associated with birth control pills? (select all that apply)**

- Increased blood pressure  
 Nausea  
 Increased risk of ovarian cancer  
 Weight gain  
 Increased risk for ectopic pregnancy  
 Stroke  
 Increased risk of cervical cancer  
 Increased risk of breast cancer  
 Blood clots  
 Increased menstrual bleeding  
 Heart attack  
 None of the above  
 Don't know

## Birth Control Pill Survey

**4. Which, if any, of the following health risks ONLY pertain to women who are over 35 and/or smoke? (select all that apply)**

- Increased blood pressure
- Nausea
- Increased risk of ovarian cancer
- Weight gain
- Increased risk for ectopic pregnancy
- Stroke
- Increased risk of cervical cancer
- Increased risk of breast cancer
- Blood clots
- Increased menstrual bleeding
- Heart attack
- Don't know
- All women are at risk

**5. Did your health care provider discuss the risks of taking birth control pills with you before giving you the prescription?**

- Yes
- No
- Other (please specify)

**6. When you filled your prescription for birth control pills, did the pharmacist discuss the risks with you?**

- Yes
- No
- Other (please specify)

## Birth Control Pill Survey

### 4. Communication

**1. Did you read the patient information insert from the pharmaceutical company that came in your package of birth control pills?**

- Yes, I read all materials thoroughly.
- Yes, but I only glanced at the materials.
- No, I did not read the materials.
- I read only the parts concerning missing a pill.
- Other (please specify)

**2. Did you read any materials from the pharmacy that accompanied your prescription?**

- Yes, I read all materials thoroughly.
- Yes, but I only glanced at the materials.
- No, I did not read the materials.
- I read only the parts concerning missing a pill.
- No materials from the pharmacy accompanied my prescription.
- Other (please specify)

**3. Do you normally read the materials from the pharmacy or pharmaceutical company when you fill a prescription?**

- Yes, I read all the information I am given about a prescription.
- Yes, I read the pharmaceutical company information but not the information from the pharmacy.
- Yes, I read the information from the pharmacy but not from the pharmaceutical company.
- Yes, but only to glance at the directions for use.
- Yes, but only if I am unfamiliar with the medication.
- No, I don't usually read the information. I trust my doctor and/or pharmacist to provide me with the information on my prescription.
- Other (please specify)

# Birth Control Pill Survey

## 5. Awareness

**1. Are you aware that there are genetic conditions that make you more likely to suffer blood clots while on birth control pills (even if you do not smoke and are not over 35)?**

- Yes, and I was aware before I began taking birth control pills.
- Yes, but I was not aware when I first began taking birth control pills.
- No
- Other (please specify)

**2. If yes, how did you become aware of these genetic conditions?**

- I had a clot.
- A family member or friend had a clot.
- I heard about it from a friend.
- My doctor told me.
- My pharmacist told me.
- I read about it on the internet.
- Other (please specify)

**3. Are you familiar with the symptoms of a blood clot?**

- Yes
- No
- Not sure

**4. If yes, please list the symptoms of a blood clot that you know:**

**5. Where did you learn about the symptoms of a blood clot?**

## Birth Control Pill Survey

**6. Please rank the following in order from most likely to least likely with 1 being most likely: From where are you most likely to obtain medical information?**

	1	2	3	4
My healthcare provider	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
My pharmacist	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The internet	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
My friends	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other (please specify)	<input type="text"/>			

**7. Would you be willing to take a blood test in order to assess whether you were at an increased risk for forming blood clots?**

- Yes  
 No  
 Not sure

**8. If yes, would you be willing to pay for this test?**

- Yes  
 Yes, but only if it were less than \$20  
 Yes, but only if it were less than \$50  
 No, I would not pay if my insurance didn't cover it  
 Other (please specify)

**9. Please share anything else about your experience taking birth control pills:**

APPENDIX E  
SURVEY RESULTS





These survey results represent the raw data that was collected before “Other (please specify)” responses were coded. The results in the manuscript represent these results combined with the results from the coded “Other” responses.



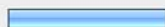

**Birth Control Pill Survey**

1. How old were you when you first started taking birth control pills?		Response Count
		324
<i>answered question</i>		324
<i>skipped question</i>		1

2. In (approximately) what year did you first take birth control pills?		Response Count
		324
<i>answered question</i>		324
<i>skipped question</i>		1

3. In what year did you stop taking birth control pills? (skip question if currently taking birth control pills)		Response Count
		158
<i>answered question</i>		158
<i>skipped question</i>		167




4. Where were you first prescribed birth control pills?			
		Response Percent	Response Count
OB-GYN office		53.4%	173
Student Health Center (college campus)		13.9%	45
Family Doctor/ General Practitioner office		16.0%	52
Planned Parenthood		10.5%	34
Other (please specify)		6.2%	20
<i>answered question</i>			<b>324</b>
<i>skipped question</i>			<b>1</b>

5. What is the main reason you were you first prescribed birth control pills?			
		Response Percent	Response Count
I asked for a prescription for birth control pills.		53.1%	172
I wanted birth control and pills were recommended by my health care provider.		12.0%	39
My doctor prescribed birth control pills for purposes other than birth control (regulate periods, taking Acutane, etc).		30.6%	99
Other (please specify)		4.3%	14
<i>answered question</i>			<b>324</b>
<i>skipped question</i>			<b>1</b>



6. Did your health care provider discuss any other birth control options with you prior to prescribing the pill?		
		Response Percent    Response Count
Yes		34.3%    111
No		61.4%    199
Other (please specify)		4.3%    14
		<b>answered question</b> 324
		<b>skipped question</b> 1

7. Prior to being prescribed birth control pills, were you asked about your family's medical history?		
		Response Percent    Response Count
Yes		85.0%    266
No		15.0%    47
		<b>answered question</b> 313
		<b>skipped question</b> 12

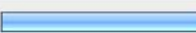
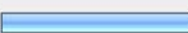



8. If yes, how were you asked about your family medical history?		
		Response Percent    Response Count
I filled it out on a form.		49.1%    135
I filled it out on a form and my health care provider discussed it with me.		42.5%    117
Other (please specify)		8.4%    23
		<b>answered question</b> 275
		<b>skipped question</b> 50

9. The following are a list of health risks, please indicate which ones you think are associated with birth control pills? (select all that apply)			
		Response Percent	Response Count
Increased blood pressure		52.4%	164
Nausea		41.9%	131
Increased risk of ovarian cancer		16.0%	50
<b>Weight gain</b>		<b>79.9%</b>	<b>250</b>
Increased risk for ectopic pregnancy		19.2%	60
Stroke		50.5%	158
Increased risk of cervical cancer		11.8%	37
Increased risk of breast cancer		18.5%	58
Blood clots		76.7%	240
Increased menstrual bleeding		7.0%	22
Heart attack		24.9%	78
None of the above	<input type="checkbox"/>	1.0%	3
Don't know		7.0%	22
		<b>answered question</b>	<b>313</b>
		<b>skipped question</b>	<b>12</b>

10. Which, if any, of the following health risks ONLY pertain to women who are over 35 and/or smoke? (select all that apply)			Response Percent	Response Count
Increased blood pressure			19.2%	60
Nausea			1.0%	3
Increased risk of ovarian cancer			8.0%	25
Weight gain			4.5%	14
Increased risk for ectopic pregnancy			5.1%	16
Stroke			30.0%	94
Increased risk of cervical cancer			5.1%	16
Increased risk of breast cancer			6.4%	20
Blood clots			28.8%	90
Increased menstrual bleeding			1.0%	3
Heart attack			21.7%	68
Don't know			19.5%	61
All women are at risk			40.6%	127
			<i>answered question</i>	313
			<i>skipped question</i>	12

11. Did your health care provider discuss the risks of taking birth control pills with you before giving you the prescription?			Response Percent	Response Count
Yes			53.7%	168
No			37.1%	116
Other (please specify)			9.3%	29
			<i>answered question</i>	313
			<i>skipped question</i>	12

12. When you filled your prescription for birth control pills, did the pharmacist discuss the risks with you?		
	Response Percent	Response Count
Yes		6.1% 19
No		86.9% 272
Other (please specify)		7.0% 22
<i>answered question</i>		<b>313</b>
<i>skipped question</i>		<b>12</b>

13. Did you read the patient information insert from the pharmaceutical company that came in your package of birth control pills?		
	Response Percent	Response Count
Yes, I read all materials thoroughly.		39.0% 122
Yes, but I only glanced at the materials.		36.7% 115
No, I did not read the materials.		16.3% 51
I read only the parts concerning missing a pill.		6.4% 20
Other (please specify)		1.6% 5
<i>answered question</i>		<b>313</b>
<i>skipped question</i>		<b>12</b>




14. Did you read any materials from the pharmacy that accompanied your prescription?			
		Response Percent	Response Count
Yes, I read all materials thoroughly.		30.7%	96
Yes, but I only glanced at the materials.		29.7%	93
No, I did not read the materials.		21.7%	68
I read only the parts concerning missing a pill.		4.2%	13
No materials from the pharmacy accompanied my prescription.		10.5%	33
Other (please specify)		3.2%	10
<i>answered question</i>			<b>313</b>
<i>skipped question</i>			<b>12</b>

15. Do you normally read the materials from the pharmacy or pharmaceutical company when you fill a prescription?			
		Response Percent	Response Count
Yes, I read all the information I am given about a prescription.		30.0%	94
Yes, I read the pharmaceutical company information but not the information from the pharmacy.		2.2%	7
Yes, I read the information from the pharmacy but not from the pharmaceutical company.		8.9%	28
Yes, but only to glance at the directions for use.		16.0%	50
Yes, but only if I am unfamiliar with the medication.		28.4%	89
No, I don't usually read the information. I trust my doctor and/or pharmacist to provide me with the information on my prescription.		11.2%	35
Other (please specify)		3.2%	10

	<i>answered question</i>	<b>313</b>
	<i>skipped question</i>	<b>12</b>

<b>16. Are you aware that there are genetic conditions that make you more likely to suffer blood clots while on birth control pills (even if you do not smoke and are not over 35)?</b>			
		<b>Response Percent</b>	
		<b>Response Count</b>	
Yes, and I was aware before I began taking birth control pills.		17.4%	54
Yes, but I was not aware when I first began taking birth control pills.		24.4%	76
<b>No</b>		<b>57.6%</b>	<b>179</b>
Other (please specify)		0.6%	2
	<i>answered question</i>	<b>311</b>	
	<i>skipped question</i>	<b>14</b>	

<b>17. If yes, how did you become aware of these genetic conditions?</b>			
		<b>Response Percent</b>	
		<b>Response Count</b>	
I had a clot.		1.5%	2
A family member or friend had a clot.		15.3%	21
I heard about it from a friend.		13.1%	18
<b>My doctor told me.</b>		<b>26.3%</b>	<b>36</b>
My pharmacist told me.		1.5%	2
I read about it on the internet.		18.2%	25
Other (please specify)		24.1%	33
	<i>answered question</i>	<b>137</b>	
	<i>skipped question</i>	<b>188</b>	

18. Are you familiar with the symptoms of a blood clot?			Response Percent	Response Count
Yes			15.8%	49
No			60.5%	188
Not sure			23.8%	74
			<i>answered question</i>	311
			<i>skipped question</i>	14




19. If yes, please list the symptoms of a blood clot that you know:			Response Count
			56
			<i>answered question</i>
			56
			<i>skipped question</i>
			269

20. Where did you learn about the symptoms of a blood clot?			Response Count
			65
			<i>answered question</i>
			65
			<i>skipped question</i>
			260

**21. Please rank the following in order from most likely to least likely with 1 being most likely: From where are you most likely to obtain medical information?**

	1	2	3	4	Rating Average	Response Count
My healthcare provider	54.5% (156)	27.3% (78)	10.8% (31)	7.3% (21)	1.71	286
My pharmacist	6.9% (20)	27.4% (79)	30.6% (88)	35.1% (101)	2.94	288
The internet	37.8% (111)	29.9% (88)	21.1% (62)	11.2% (33)	2.06	294
My friends	5.1% (15)	17.8% (53)	36.4% (108)	40.7% (121)	3.13	297
Other (please specify)						32
<b>answered question</b>						<b>311</b>
<b>skipped question</b>						<b>14</b>

**22. Would you be willing to take a blood test in order to assess whether you were at an increased risk for forming blood clots?**

		Response Percent	Response Count
Yes		82.3%	256
No		7.1%	22
Not sure		10.6%	33
<b>answered question</b>			<b>311</b>
<b>skipped question</b>			<b>14</b>









23. If yes, would you be willing to pay for this test?			Response Percent	Response Count
Yes			21.6%	62
Yes, but only if it were less than \$20			32.1%	92
Yes, but only if it were less than \$50			13.6%	39
No, I would not pay if my insurance didn't cover it			27.2%	78
Other (please specify)			5.6%	16
			<i>answered question</i>	<b>287</b>
			<i>skipped question</i>	<b>38</b>





24. Please share anything else about your experience taking birth control pills:		Response Count
		81
		<i>answered question</i>
		<b>81</b>
		<i>skipped question</i>
		<b>244</b>

APPENDIX F


RESPONSES TO QUESTION 24

*“Please share anything else about your experience taking birth control pills:”*

	Comment Text	Response Date
 <b>Find</b>	1. Sometimes hard to remember to take them every day.	Wed, 2/18/09 9:17 PM
 <b>Find</b>	2. I have has issues with it not wanting to work after 3 to 6 months of use. At one point last year with being on the pills i was getting double periods. Which made mt OB put me on the ring and still having a few issues with that. None other than he wanted me to use it continuous for three months issuing a new ring every month and on the third month have your cycle and then start over, well I have only made it to two months... But at least I am not having to cycles a month!	Wed, 2/18/09 6:31 PM
 <b>Find</b>	3. It regulated my menstrual problems well. I didn't expect it, but I felt emotionally happier. Yet my closest friends and family complained that I was acting very strange and depressed. This is why I quite taking the pill.	Wed, 2/18/09 4:57 PM
 <b>Find</b>	4. I think it is not considered a big deal by the medical community. I wondered after being on the pill so long if there were any affects, but have had difficulty getting doctors to even discuss this.	Wed, 2/18/09 3:40 PM
 <b>Find</b>	5. I am currently not taking birth control pills in order save some money on prescription medications. I have stopped taking all nonessential prescription and OTC medications. I may take generic birth control pills again in the near future but before I do I may research a bit on this blood clot issue.	Wed, 2/18/09 2:15 PM
 <b>Find</b>	6. I was young (18). I smoked. I developed veins in my legs. I feel this is due to the combo of smoking and taking bc pills	Wed, 2/18/09 6:25 AM
 <b>Find</b>	7. I didn't know that it will enlarge the cysts i currently have in my breast.	Tue, 2/17/09 8:33 PM
 <b>Find</b>	8. It has taken me a long time to find a pill that works well with my body - I suffered from nausea on a daily basis.	Tue, 2/17/09 1:12 PM


-  **Find** 9. severe mood swings Mon, 2/16/09 8:51 PM
-  **Find** 10. I developed a blood clot. My PCP would not perform a test to understand why the blood clot happened. He said that if I were planning to have children, I should have the test and figure out why the clot happened, but would not recommend it otherwise (reason: I would worry needlessly). After I had the clot, I stopped taking the pill and had an IUD implanted. I have not (to my knowledge) had any problems since. Mon, 2/16/09 5:37 PM
-  **Find** 11. You should ask a question about whether the pills were prescribed in the first place. Usually they are, but in some cases, you may get them another way. Its not the way things are supposed to be done, but it happens. Mon, 2/16/09 1:43 PM
-  **Find** 12. I'll start by saying that I am a normal, healthy 25 year-old woman. I eat a healthy diet low in refined carbohydrates and saturated fats, and I work out 5-6 days per week. All things aside, my health is always a concern b/c of my experience on birth control pills. My experience on birth control pills, the Nuvaring, or Depo-Provera all proved to be horrendous. I stopped having periods, developed crappy symptoms, gained weight, and eventually was diagnosed with Polycystic Ovarian Syndrome (PCOS) in 2007. I stopped taking birth control that year and went through a series of naturopathic supplements in order to regain my normal menstrual function. It has taken me over a year to begin having cycles again. I think birth control came straight from hell and I hate, hate, hate it. I would rather undergo chinese water torture daily than take birth control, and that is the God's honest truth. I think doctors and pharmaceutical companies owe it to patients to be more forthright about the risks women are taking on by messing with their body's natural rhythms like that. It may work for some women, but I know a great many women who have developed lifelong issues as a result or in part due to taking the faux hormones in birth control pills, shots, or rings. It's really sad, but life is not some stupid Loretta Lynn song about "I've got the pill." The pill doesn't solve every problem, and for me, it created a great many additional problems. My fertility has been affected Mon, 2/16/09 8:58 AM

forever by my under informed choice to go on birth control, and by the irresponsible doctors who encouraged me to switch methods rapidly "until I found what worked for me." Nothing worked - the reason being because my body doesn't handle birth control well. It makes me suicidal, angry, bloated, moody, and just miserable - every. single. day. Like I said...I'd just as soon go under some form of Guantanamo-level torture before I'd ever, ever, ever, ever, EVER go on birth control again. If and when my husband and I have kids of our own (I say IF because with my PCOS, my fertility has been so affected that we may never be able to concieve our own children, sadly...thanks, birth control!) and we decide we're done having children, he's agreed to get a vasectomy (since I've been through enough already, he says).

- 


**Find**

**13.** I've never had a problem...they have been very effective in treating my period problems (heavy bleeding, intense cramping) and in dealing with acne. I stopped taking them in order to get pregnant and plan to start back as soon as I have the baby and am done breast feeding.

Sat, 2/14/09 9:07 PM
- 


**Find**

**14.** The hormones in the pill caused drastic mood swings that eventually prompted me to stop taking the pill.

Sat, 2/14/09 10:27 AM
- 


**Find**

**15.** Never had a problem.

Fri, 2/13/09 11:38 PM
- 


**Find**

**16.** I am glad to have other options now that I am older and have children.

Fri, 2/13/09 7:26 PM
- 


**Find**

**17.** I stopped taking birth control pills because I didn't like the feeling of having chemically regulated hormones. Thus, my current birth control is non-hormonal.

Fri, 2/13/09 2:08 PM
- 


**Find**

**18.** It was never explained why the particular prescription I was given was chosen over other available options/options were not described or discussed

Fri, 2/13/09 1:28 PM
- 


**Find**

**19.** They give me mood swings that are more severe than when not taking them.

Fri, 2/13/09 12:16 PM
- 

**Find**

**20.** very positive experience





Fri, 2/13/09 11:05 AM
- 

**Find**








**21.** I would be interested in learning about the number of women who have had miscarriages and the







Fri, 2/13/09 10:07 AM


correlation with birth control and the length of time birth control was taken. There may be no correlation, but the number of women who are having miscarriages is alarming.


-  **Find** 22. I stopped them because they made me moody. I will not take birth control anymore because I know it increases risk of breast cancer. I think my gynecologist (and GYNs in general) are biased toward giving birth control to people despite the risks. My current gynecologist completely downplayed any risks associated with hormonally-based birth control, so I do not trust her (or most doctors for that matter). Fri, 2/13/09 9:29 AM
-  **Find** 23. Also was on the Ortho Evra Patch for a time...this proved to be a bigger clotting risk than ORAL contraceptives and worth your time in reading about. Fri, 2/13/09 6:51 AM
-  **Find** 24. I've been really happy with the pill I've been on for years and years. I sometimes wonder if it will effect me having kids or any other negative effects, but I guess I'll find out later. So far, it's been great and I'm very happy. Thu, 2/12/09 10:55 PM
-  **Find** 25. Through a college health center my birth control brand was changed numerous times due to change in insurance policy. The pharmacist assured me they were all the same, some were just generic. I was not told of any changes in hormone dosage. They changed the brand at least three or four times in only a few months. During that time I experienced extreme mood swings, depression, and anger. My mood would change so drastically I considered seeing a therapist because I was concerned I had a chemical imbalance. I went to the same college health center for an annual pap smear and told the nurse practitioner about the changes in birth control brands and my extreme changes in mood. She had to check on the database to see exactly what they kept changing. When she saw the hormone differences in prescriptions she actually gasped. Apparently the changes in brand of birth control did NOT have the same hormone level despite what the pharmacist told me. She then prescribed me a brand that was low in hormone levels and on my Thu, 2/12/09 10:30 PM


insurance plan. My moods are not as crazy as they once were. This was an extremely draining time in my life when they kept changing the prescription. I can't say it was due to the birth control but I honestly think it was.


-  **Find** 26. I am not currently on birth control pills. I do not think that the risks are worth it. Thu, 2/12/09 10:13 PM
-  **Find** 27. Taking a pill on a daily basis was difficult so I switched to the birth control patch, which I am currently using. Thu, 2/12/09 9:26 PM
-  **Find** 28. I started taking Yaz to induce menstration at age 22. I began menstruating fairly normally for a few months and then bled excessively for 30 consecutive days. One of the side effects of note in my case was breast enlargement. It was such a drastic change that people thought I had undergone breast enlargement surgery. After bleeding so much, my gynecologist changed me to the Ortho-evra patch. I did fairly well on this, however my mood changed a lot. In the end, my husband and I decided that birth control was not for us. Thu, 2/12/09 7:20 PM
-  **Find** 29. I think there is still confusion about whether it's a good idea to take BC pills when you know you want to try to become pregnant in a few months...how long a woman should be off the pill is still inconsistent among doctors. Also, at what point can perimenopausal woman stop taking the pill? I don't see these issues addressed well publicly. Thu, 2/12/09 4:14 PM
-  **Find** 30. Due to thyroid problems (I assume), I can only take pills that are consistent dosages throughout the month, which I did not realize until I tried ones that didn't work when I was 17. Also, I was put on the pill at 11 because my thyroid problem was undiagnosed. Thu, 2/12/09 3:47 PM
-  **Find** 31. emotional roller-coaster, weight gain, very irritable Thu, 2/12/09 3:32 PM
-  **Find** 32. I was miserable. I never knew there were options for the strength of hormones in the pills. I stopped taking them because I was sick and because I learned of two friends who had strokes after taking a form of BC. Thu, 2/12/09 2:00 PM

-  **Find** 33. When I went off the pill, I realized how much they affected my personality. Everyone discusses how they ease PMS symptoms and etc., but after going off the pill I was much more relaxed, my husband and I fought less and my periods were actually lighter. Also, in contrast to the tale that you lose weight when going off the pill, I gained 5-7 lbs, quickly. Since i had been on the pill for such a long period of time, almost 20 years, I always believed my periods were heavy when, in fact, they are quiet light. I will never go back on the pill. Doctors are much to quick to prescribe and dismiss side effects or even give any credit to some of the emotional effects I felt the pill caused, such as, irritability, short temper--much these negative emotions disappeared after I ceased taking the pill. Thu, 2/12/09 1:28 PM
-  **Find** 34. I think the experience taught me to take responsibility for myself. My dad is the one who actually wanted me to start taking them and even though I was 16, it was a great choice. I am 25 and have never had a pregnancy scare, which is good for me because I am not ready for children right now. Thu, 2/12/09 12:55 PM
-  **Find** 35. had no problems Thu, 2/12/09 12:16 PM
-  **Find** 36. I am 44 & have taken the lowest dose of BCP for 28 years. I'd rather not take them, but fear problems if I stop after all this time, and fear a pregnancy. Thu, 2/12/09 11:31 AM
-  **Find** 37. Due to the estrogen in the birth control pills they are not a good option for anone with bi-polar or similar emotional imbalances, I wish they would make a pill that worked without the hormones Thu, 2/12/09 10:49 AM
-  **Find** 38. I was shocked- and grateful- when I finally found a doctor who discussed alternatives with me, suggested a wide variety of reading, and let me then do my research and make my own decision before wiring a prescription. After doing the reading, there is no way I will ever take another birth control pill in my life. Every other doctor I had acted like it was giving out Altoids, and I always looked at it that way myself as a result- until meeting a new doctor. Thu, 2/12/09 1:24 AM

 **Find** 39. I've had two different GYNs give me completely contradictory information about the side effects and dangers of BCPs. (My discussions were related to problems with a friable cervix.) Overall, I'm surprised at how little doctors seem to know about female BCP - I haven't experienced this amount of ambiguity with any other medical specialty or problem. Wed, 2/11/09 11:45 PM









 **Find** 40. Birth control pills have changed significantly since I have taken them. Also, public knowlege has changed significantly. Years ago, physicians were only mildly concerned with finding the appropriate dosage for each patient. Now there seems to be more interest in finding the right pill for each patient, if possible. While my length of time taking the pills extends from 1971-1982, I had three full term pregnancies during that time, so my exposure was less than someone who has taken birth control pills for an extended period of time with no breaks. I am sure that if I were to be prescribed birth control pills today, I would be much more skeptical and wary about taking them at all. Being post-menopausal, I am only glad that I did not take hormone replacement therapy 10 years ago when it was first prescribed for me. At that time, it was the standard, more or less with most physicians advocating HRT as beneficial to women to prevent heart disease. I was not comfortable with that and then, 2 years later, new studies were published showing that HRT is not even a good idea in most instances. Everyone needs to be their own best advocate whether is is birth control pills, or blood pressure medicine. Doctors usually follow the "tide" of current thinking and they are not always correct. Wed, 2/11/09 9:46 PM

 **Find** 41. I had virtually no symptoms other than a regulated, expected period. I switched to a few different pills over the 13 years I took them. When I started taking them, my migraine headaches stopped. Wed, 2/11/09 9:43 PM










 **Find** 42. I started taking them over 20 years ago and stopped to get pregnant after 5 years, so some of my memories about the information I got are sketchy. I als think the information on risks has changed some in the past 20 years and I have not Wed, 2/11/09 9:10 PM




paid as much attention since I no longer take anything.


-  **43.** Originally started taking pills to decrease menstrual cramps- helped a LOT (and still does); now, main benefit is birth control. Wed, 2/11/09 8:45 PM
-  **44.** I was too young and too absent minded when I took the pill. I never took them consistently, so I finally just stopped. Wed, 2/11/09 8:43 PM
-  **45.** Over time it began to cause sever mood swings, and irrational emotional symptoms. I also believe it can be a cause of breast cancer. After eight years I have stopped taking them. I would recommend other forms of contraceptives to friends/family besides the pill. Wed, 2/11/09 8:36 PM
-  **46.** I think they're too often the first option doctors prescribe for reasons other than birth control. That's frustrating. They're not a magic pill and some doctors seem to think they are. Wed, 2/11/09 8:35 PM
-  **47.** It caused my post partum depression...I had been taking the same pill for 10 years and after my 3rd child it caused the hormonal imbalance and it caused hte depression I had to go off of it and 2 days later it was fine. I had never heard that before... Wed, 2/11/09 7:46 PM
-  **48.** Only took the pill for a couple of years and that was about 30 years ago. Thankfully, I don't have that to worry about any more! Wed, 2/11/09 7:45 PM
-  **49.** I liked being on BCPs for the amenorrhea but I did worry about my health once I reached age 35 (and before) which lead me to discontinue use at age 38. I know there are lots of associated risks (as with ANY medication) but, at the time, the benefit outweighed the risk. However, I become more informed as I got older and because of my profession. I do not feel that my healthcare providers 15 years ago stressed the need to educate myself on the risks of taking BCPs. We discussed not missing pills and the risk of pregnancy, not the risk to my health. I was lucky during those uneducated years that no devastating side effects occurred. Wed, 2/11/09 7:28 PM
-  **50.** It infuriates me that most insurance companies do not pay for BC pills anymore, but they WILL pay Wed, 2/11/09 7:18 PM


for Viagra!! I think unwanted pregnancies and cost of raising those children should have more priority!


-  **Find** 51. In reference to question number seven, I have a family history of a genetic mutation Factor V Leiden that increases the risk of blood clots and my sister was told that she could only take certain types of birth control as a result of her having this mutation. I decided to have the test before I started any form of birth control. Luckily for me, I didn't have the mutation and this was information I provided to my OB-GYN when I asked for a prescription for birth control. Wed, 2/11/09 6:21 PM
-  **Find** 52. It made me so moody and irritable that I stopped taking it. Wed, 2/11/09 6:17 PM
-  **Find** 53. I experience none of the "normal" side effects, unless I miss a pill. Wed, 2/11/09 5:48 PM
-  **Find** 54. I've been on and off bc since I began in 1990 for different reasons not just preventative measures. Wed, 2/11/09 5:12 PM
-  **Find** 55. I don't understand the commercials for the nuvo-ving whose main argument for switching is that you don't have time to take a pill every day. I mean, really? You don't have time to take ONE pill?? Wed, 2/11/09 5:12 PM
-  **Find** 56. I wasn't told herbs can interrupt the pills and I have a Son to prove it. Wed, 2/11/09 5:02 PM
-  **Find** 57. I had extremely irregular periods and heavier bleeding. I also had a negative hormonal reaction Wed, 2/11/09 5:01 PM
-  **Find** 58. I really love it because I had the worst cramps and PMS. I am anemic and the pill really helps. Also knowing that if I use a second form of birth control I'm pretty much clear of getting pregnant while on the pill. Very reassuring. Wed, 2/11/09 5:00 PM
-  **Find** 59. I feel like very limited information is provided to women regarding how birth control pills actually work. The more information I found about how the pills worked and what some side-effects could be, the less comfortable I am with them. I feel similarly about the IUD. That being said, I believe that many healthcare plans continue to be sexist with their coverage of birth control--for example by allowing coverage for vasectomy and/or viagra Wed, 2/11/09 4:46 PM


but not for birth control taken by women.

 **60.** I did gain some weight - about 5-7 lbs. I went off the pill because of headaches and because I was getting married and wanted kids. I don't think the headaches had anything to do with my pill because I still have the headaches and they are due to temporomandibular joint disorder and not migraines. Wed, 2/11/09 4:21 PM






 **61.** I've taken many different kinds over the years. I wish they were more clear about what types & amounts of things are in them (progestin, synthetic versions, estrogen, androgens) and what the likely side effects are for these specific ingredients. Androgens can be VERY unhealthy for lots of women, and for some cause hair loss (which no one seemed to know when I experienced this and told my own health care provider about it). I just wish there was a chart of all the BC options with ingredients listed and their possible effects listed. I don't understand why we aren't presented with that information and allowed to have a voice in which prescription we get. Wed, 2/11/09 4:18 PM

 **62.** The first pill I tried (YAZ) I reacted to within 48 hours. Heart racing, mind would not stop running, chest tightness. A month later I tried tri-cyclen low. On day 11, one arm was numb, I could not raise my arm very high, I had no strength in the arm, and I could not think of common words. I went to Urgent Care and the physician determined it was highly probably due to the BC pills. I stopped taking them. I have gone back to a copper IUD. This experience occurred when I was 39 and I had never taken BC pills before, nor will again. I took them against the advice of my brother, a medical professional, whose friend died of a stroke brought on by BC pills. He definitely took the opportunity to remind me that he'd been right! Wed, 2/11/09 4:16 PM








 **63.** Even though I know the symptoms and risks associated with it, I still use birth control and have for 9 years. I will probably get off of them soon. Wed, 2/11/09 4:04 PM

 **64.** Health insurance coverage of specific types of BC pills seems to change frequently - for example, I've been on three different brands within the last year. My doctor has not told me of this switch, Wed, 2/11/09 3:44 PM






rather it is the pharmacist that has notified me of the change (pharmacy is a part of the larger medical system). Usually the notification is "we are changing your type of birth control pill - please let us know if you have any questions" rather than a full description of what (if anything) is different about the pills they are switching me to. Since one of the switches involved going from a tri-cyclic to a constant dose (without explanation of what that means for my particular concerns - blood pressure and dysmenorrhea), I was not satisfied with the interactions described above.

-  **65.** No doctor ever talked to me about lots of options for birth control. It was just "you want the Pill? ok, here you go." Wed, 2/11/09 3:33 PM
-  **66.** I wish my doctor had told me more of the risks and discussed it with me more. That is why I read the pamphlet that came with it so carefully... After I had been taking BC pills for about 3 months I heard of a friend who had blood clots from it and then I re-read the pamphlet. I would LOVE it if there was a way for me to know how much at risk I am for something like blood clots. I would be willing to pay up to probably \$250 to find out if it was a fairly sure thing (that I knew it would be helpful). I am concerned about getting clots because I know it is not extremely uncommon with birth control. Thanks for doing this research. I hope it will help many women to know the risks and be wise in their decisions. Wed, 2/11/09 3:27 PM
-  **67.** Changed pills many different times due to not good fit for body/acclimation. Decided to quit taking as had gone through so many with side effects(non-serious). Wed, 2/11/09 3:16 PM
-  **68.** I stopped taking BC pills in August of 2004 b/c I felt that my hormones/emotions were out of control. I had been taking orthocyclin at the time and had been on that pill for a few years. I recently started taking them again (2009) after having a baby b/c I wanted to use a different form of BC. I'm on a different RX, so I'll see how this goes. Wed, 2/11/09 3:14 PM
-  **69.** I recognize the importance of this study, however, most of the questions are in reference to when I first was put on birth control. Since that time (16 Wed, 2/11/09 3:05 PM

years old), I have moved and switched doctors on several occasions and they all handle the process differently. To be honest, I don't necessarily remember if I received information when I first got prescribed - that was over 14 years ago.

-  **70.** i had to come off birth controls due to depressive symptoms. they symptoms lifted immediately after 30 days of coming off b/c pill. Wed, 2/11/09 2:58 PM
-  **71.** I HATED IT! BC makes me crazy. I have a copper IUD that suites me well and does not alter my emotional state whereas taking hormones does. And, for some reason, I'm more comfortable with "blocking" or combating sperm with scary copper rather than messing with the hormone balance of my body and tricking it into believe it's perpetually pregnant. Wed, 2/11/09 2:43 PM
-  **72.** i started gaining weight when i started the pill. therefore i quit taking it and decided to endure cramps. Wed, 2/11/09 2:28 PM
-  **73.** I liked them, especially Seasonale, which reduces menstrual periods to four per year. Wed, 2/11/09 2:27 PM
-  **74.** I took the pill for twenty or so years. I stopped taking them the minute I was married in hopes of starting a family. I was unable to become pregnant. I ran out of eggs. I personally believe girls/women should NOT stay on BC pills for extended periods of time, I believe the pill is the reason so many people in the 40-50 age range today are unable to have children. I think back in the 70's we did not have enough information, and now we are paying the price by being infertile. Wed, 2/11/09 2:25 PM
-  **75.** I was not aware, in 2003, when I loaded up on vitamins and herbal supplements that they could change the effectiveness of the pill...hence, my son! The last time I did purchase the pill it did have a sticker referring to that but I am not sure how aware ladies are of that issue. Wed, 2/11/09 2:20 PM
-  **76.** I experienced bilateral pulmonary embolisms when I was taking birth control pills. It turned out that I had factor V Leiden (homozygous), but my family was unaware of our genetic condition until I had my clots. I can't remember my doctor ever discussing blood clot risks with me when Wed, 2/11/09 2:11 PM

prescribing BCPs. My grandfather had had a stroke, but I don't recall discussing that. I originally took Ortho Tri-cyclen, but the doctor (at the student health clinic) switched me to Mircette to help with migraines. It turns out this is one of the types of BCPs that causes the greatest risk for clots.

-  **77.** Discontinued use of pills in favor of other birth control methods, including patch and shot. Wed, 2/11/09 1:59 PM
-  **78.** My experience with trying to take depo has been frustrating because some health care providers are against it (because it ceases menstruation), and it is not as well covered by insurance. Also, some doctors are not diligent about making sure patients stay on schedule, or following up with options when a shot is missed. I feel like there is a huge amount of stigma associated with birth control and which type you take, and how you are perceived by your health care provider, friends and others based on your choice. I feel like there are several facts and myths about birth control that the public needs to be educated on. For example, there is a perception out there that it is unhealthy to miss your period due to medication like depo. Wed, 2/11/09 1:59 PM
-  **79.** they made me a moody bitch! Wed, 2/11/09 1:40 PM
-  **80.** It's hard for me to remember everything that happened when I was 19, but I do remember that, independent of telling me that I was fat, my doctor was good and left me feeling informed. I also remember being on the look out for blood clot symptoms after starting the pill. But I was not tested for any pre-existing conditions to make sure it was safe for me. Wed, 2/11/09 12:53 PM
-  **81.** i stopped taking them in 2008. I did find that taking them made my period lighter and more managable. I have not felt that much different being off it the pills. Wed, 2/11/09 12:38 PM

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