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VERDICT

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Special Women's Health Issue

VERDICT
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Women are More Likely than Men to Suffer Adverse Drug Events

Studies by the Agency for Healthcare Research and Quality (AHRQ), a division of the U.S. Department of Health & Human Services, found that women take a larger number of medications and use more medications than men. Women also respond differently to medications than men and are more likely to experience medication-related injuries (adverse drug events).

The difference in response to medications between men and women may be because women have lower body weight, smaller organ sizes and a higher proportion of fat compared with men. Women also have differences in metabolism such as functional variations in liver and kidneys and slower gastrointestinal metabolism. Hormones and their levels also differ between men and women, affecting the way medications are processed, absorbed and eliminated by the body. Women's hormones at different stages of life or blood levels during menstruation and pregnancy also influence a medication's effects.

Another factor of medication-related injuries or adverse drug events happens when women concurrently use two or more medications (including over-the-counter [OTC] drugs, dietary supplements and herbal products) or between medications and certain foods or beverages.

"Women should be proactive about their medication use," says Rosaly Correa-de-Araujo, M.D., M.Sc., Ph.D., Senior Advisor for Women's Health at the Agency for Healthcare Research and Quality. She recommends that, "Women take responsibility for their own health and ask clinicians questions about diagnosis, treatment and medication use."

According to the Agency for Healthcare Research and Quality (AHRQ) women should:

- Understand the need for each medication and take them correctly at the right dosage and time of day. Ask

their doctor or pharmacist before crushing or splitting medications.

- Ask their doctor or pharmacist about side effects, particularly those requiring immediate medical attention, and about potential interactions with other prescription medications, OTC medications, dietary supplements, herbal products, food and beverages.
- Ask their doctor or pharmacist about the need to stop taking medications before surgery, as certain medications (including herbal products) can interfere with anesthesia or blood clotting.
- Maintain a current list of all prescription medications, OTC drugs, dietary supplements and herbal products being used and make that current list available to doctors during checkups, regular office visits, hospitalizations and emergency situations. Because women generally see more than one doctor, communication is important to help ensure proper medication use.
- Inform their doctor and pharmacist about any allergies to medications.
- Inform their doctor if they are pregnant or intend to become pregnant in the near future. Not only does pregnancy alter a medication's effect, certain medications can cause birth defects.
- Inform their doctor and pharmacist if they feel their medications are working differently during different parts of their female cycle.
- Read the U.S. Food and Drug Administration (FDA)-approved drug package inserts for all prescription and nonprescription medicines. Be aware that herbal products are not FDA approved.

Despite the fact that studies show women consume a larger number of medications and use more medications than men, women are underrepresented in clinical drug studies. Medications approved by the U.S Food and Drug Administration (FDA), unless specifically tested for women, may have different optimal dosages or cause unknown adverse drug events in women.

If you have experienced or a loved one died from a medication-related injury or adverse drug event, you may be entitled to compensation for your injuries or a loved one's death. Attorneys at Napoli Bern Ripka, LLP are experienced in dangerous prescription drug litigation and fight for you against the big drug companies.

Reports of Serious Injury and Death with Birth Control Yaz®

Yaz® is the brand name for a relatively new birth control pill that is a combination of progestin hormones (drospirone/ethinyl estradiol) along with other components and is manufactured by Bayer Healthcare Pharmaceuticals, Inc. It is the top-selling women's contraceptive in the United States with more than $600 million in sales in 2008. This high number in sales may be attributed to the fact that Bayer's promotional campaign for Yaz has been claiming some unusual benefits for its users.

The ingredients in Yaz are a powerful diuretic and can significantly increase potassium levels. However, this new drug seems to carry with it some unusually high health risks as well. The makers of Yaz birth control for women are claiming that the contraceptive, besides preventing conception, also helps reduce the symptoms of acne, relieves irritability and moodiness, helps fatigue, headaches, bloating and muscle aches. Bayer's television advertisements also claim that Yaz relieves the symptoms of PMS (premenstrual syndrome) and will alleviate the problem of increased appetite. Sounds like a miracle pill for women, doesn't it? The problem with this advertising campaign is that the U.S. Food and Drug Administration (FDA) did not approve Yaz for use with these symptoms.

In February 2009, the FDA and 27 State Attorney Generals announced that a settlement had been reached with regard to a lawsuit against Bayer Healthcare for implying in their commercials that Yaz could be used to treat the above-mentioned symptoms for which Yaz was not approved. This settlement is an addition to the 2007 Judgment against Bayer for misleading advertisements for the drug Yaz and for minimizing the health risks associated with the use of Yaz.

The FDA did approve Yaz for treating certain types of moderate acne and it was approved for treating PMDD (premenstrual dysphoric disorder) and of course, pregnancy. The commercials however claimed much more in the way of treatments or cures and while distracting music is played, the health risks were minimized. The settlement requires Bayer to invest $20 million to make new commercials and the company must submit those commercials to the FDA for approval prior to being aired.

Women, doctors and other healthcare providers have reported a wave of serious Yaz associated injuries and deaths that include blood clots, pulmonary embolism, stroke and heart attack. In addition, some women have been reporting gall bladder disorders and removals, kidney stones and deep vein thrombosis. In some cases, the women were simply taking the drug to control their acne, but as a result suffered increased potassium levels that led to gallbladder damage and removal. Other women suffered blood clots and sudden death as a result of taking the pill for the PMS related systems of emotional discomfort. Other side effects of Yaz include liver damage, depression, migraines, breast lumps, vaginal bleeding, high blood pressure, high cholesterol, chest pain, confusion, coughing blood and severe allergic reactions. Some of these women were not even old enough to bear children yet. These adverse side effects and injuries have spurred a large number of lawsuits filed on behalf of the victims in what is the becoming known as the newest mass tort.

If you or someone you know is taking Yaz and have had any of the adverse side effects associated with this drug, you may be entitled to compensation. Contact Napoli Bern Ripka Law Firm by calling toll free 1-888-529-4669.

Have You Experienced Life-Threatening Side Effects of the Birth Control Pill Yasmin®?

Yasmin® is the brand name for a birth control pill that is generically known as drospirenone. It is also a treatment for moderate acne and premenstrual dysphoric disorder (PMDD) in women. Berlex Laboratories, Inc. (This name changed to Bayer Healthcare Pharmaceuticals in 2008.) produces Yasmin as an oral contraceptive. Yasmin works to prevent pregnancy by changing the lining in a woman's cervix making it difficult for sperm to reach an egg and in the uterus making it hard for a fertilized egg to attach to the uterine wall. Yasmin is 99% effective in preventing pregnancy and has brought Bayer Healthcare $487 million in sales in the US alone with $1.5 billion worldwide. However, it has also been reportedly causing some serious side effects since the FDA approved its use in May 2001. Bayer Healthcare also manufactures Yaz birth control pills.

The main difference between Yaz and Yasmin is in the level of estrogen contained in each pill compared to the level of progestins, specifically desogestrel. Yasmin contains a higher dose of ethinyl estradiol (estrogen) at 30 mcg, while Yaz has only 20 mcg of estrogen. The dosing schedule is different for Yaz as well. Patients are told to take pills with the active ingredient for 24 days and then take the placebo pills for only 4 days. Most contraceptive pills including Yasmin are on a schedule of taking the pill for 21 days and then 7 days of taking the inactive pill. However, this dosing schedule does not appear to relate to the side effects associated with Yaz.

Studies have shown that Yasmin is more dangerous than its predecessor contraceptives containing progestins that are used to prevent pregnancy. Yasmin increases potassium levels to dangerously high levels, which can create some serious problems with regard to normal heart rhythms and other body functions related to salt and water balance. It also slows down blood flow, which contributes to the forming of blood clots. When these blood clots travel to the lungs or the brain, they become serious strokes or pulmonary embolisms. Other side effects include breast lumps, depression or mood changes, heart attack, high blood pressure, kidney and/or liver damage, migraines, vaginal bleeding and severe allergic reactions including swelling, hives and difficulties in breathing.

If you are taking Yasmin and experience abdominal pain, localized skin swelling or pain, feelings of despair, chest pain, confusion, lightheadedness, breathing difficulties, numbness in the extremities or on one side of your body or any vision problems, seek emergency medical care immediately. This may be a life-threatening situation. In addition, if you or someone you care about has been injured from the use of Yasmin, please consult with one of the attorneys at Napoli Bern Ripka Law Firm by calling 1-888-529-4669. You may be entitled to compensation.

Hormone Replacement Therapy HRT Risks

Hormone Replacement Therapy (HRT) is a prescription drug therapy using one or more female hormones, commonly Estrogen alone, Estrogen plus Progesterone/Progestin (synthetic progesterone) and sometimes testosterone to treat symptoms of menopause such as hot flashes, vaginal dryness, mood swings, sleep disorders, decreased sexual desire and prevention of osteoporosis.

HRT with Estrogen alone comes in the following forms: nasal spray, pills or tablets taken by mouth, skin gel or patches, vaginal creams, vaginal tablets or vaginal ring and is usually prescribed only for women who have undergone a hysterectomy or removal of the uterus.

Women who have not had their uterus removed are prescribed Estrogen plus Progesterone/Progestin HRT, also called combination therapy. This form of HRT combines doses of Estrogen with Progesterone/Progestin to reduce the risk of endometrial (uterine) cancer. This therapy comes in the following forms: pill, skin patch and vaginal cream.

Hormone Replacement Therapy is not recommended for women who smoke cigarettes, have active or past incidence of breast cancer, recurrent or active endometrial cancer, abnormal vaginal

bleeding, recurrent or active blood clots, liver disease or history of stroke.

A study by the Women's Health Initiative (WHI) Hormone Program, which was sponsored by the National Institutes of Health (NIH) divisions of National Heart, Lung, and Blood Institute (NHLBI) and the National Cancer Institute (NCI), examined the effects of hormone replacement therapy on women's health. The WHI Hormone Program involved two studies, the Estrogen plus Progestin Study for women with a uterus and the Estrogen Alone Study for women without a uterus. In both hormone therapy studies, women were chosen randomly to receive either the hormone medication being studied or the placebo.

The Estrogen plus Progestin Study was stopped in May 2002 when the WHI Data and Safety Monitoring Board reviewed the study data and saw a 24% increased risk of invasive breast cancer in women taking Estrogen plus Progestin. The Board also saw increased risk of heart disease, stroke, blood clots and urinary incontinence. Therefore, in the judgment of the Board, the overall risks outweighed the benefits of taking Estrogen plus Progestin, specifically Prempro®.

The WHI Estrogen Alone Study, which involved Premarin™, was stopped in February 2004, when the researchers concluded that Estrogen alone increased the risk of stroke and blood clots.

A Women's Health Initiative (WHI) Memory Study also found that Estrogen plus Progestin HRT in postmenopausal women age 65 and older doubled their risk of developing dementia. The risk increased for all types of dementia, including Alzheimer's disease.

Finally, a study published in the March 5, 2008 issue of the Journal of the American Medical Association reported on WHI participants three years after they stopped Estrogen plus Progestin HRT. The researchers found that "many of the health effects of hormones such as increased risk of heart disease are diminished, but overall risks, including risks of stroke, blood clots and cancer remain high."

If you have been diagnosed with breast cancer, heart disease, stroke, blood clots or urinary incontinence and have ever been on Estrogen Alone or Estrogen plus Progestin hormone replacement therapy, you may be entitled to compensation. Call Napoli Bern Ripka, LLP today at 888-529-4669 to discuss your legal options.

Wyeth Deceived Doctors and Women about Prempro® Dangers

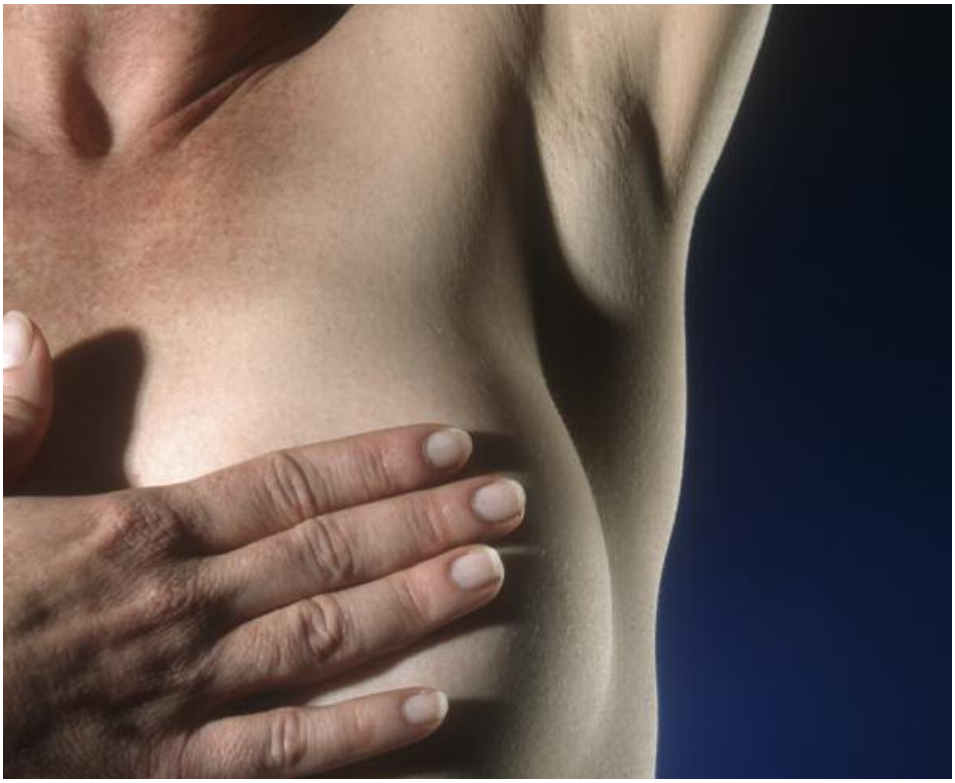
PREMPRO® (conjugated estrogens/medroxyprogesterone acetate tablets) is a Hormone Replacement Therapy (HRT) drug manufactured by Wyeth Pharmaceuticals and prescribed for women who have a uterus to reduce symptoms of menopause such as hot flashes, vaginal dryness, itching and burning and prevention of osteoporosis (thin weak bones).

In the 1970's, Estrogen alone drugs prescribed for menopause symptoms, such as Premarin also manufactured by Wyeth Pharmaceuticals, were found to increase risks of endometrial cancer in women who had not undergone a hysterectomy or removal of the uterus, sales of Premarin and cases of endometrial cancer dropped.

A few years later, Wyeth revitalized Premarin sales by recommending doctors prescribe Premarin with a Progesterone/Progestin, such as Provera manufactured by Pharmacia & Upjohn Co, to alleviate risks of endometrial cancer.

In 1995, Wyeth gained approval from the U.S. Food and Drug Administration (FDA) and released an Estrogen and Progestin combination HRT in a single pill called Prempro. Wyeth marketed the drug to women as a "Fountain of Youth" to prevent heart disease, osteoporosis, Alzheimer's disease, depression and low sexual libido.

In 2002, a Hormone Replacement Therapy study by the Women's Health Initiative (WHI) was stopped after study data showed a 24% increased risk of invasive breast cancer in women taking Estrogen plus Progestin, specifically Prempro. The study data also showed an increased risk of heart disease, stroke, blood clots and urinary incontinence. A Women's Health Initiative (WHI) Memory Study also found that Estrogen



plus Progestin HRT in postmenopausal women age 65 and older doubled their risk of developing dementia. The risk increased for all types of dementia, including Alzheimer's disease.

These study findings were directly opposite of Wyeth's drug claims about their Prempro drug. Prempro sales plummeted.

According to a December 12, 2008 article in the *New York Times:*

Wyeth, the pharmaceutical company, paid ghostwriters to produce medical journal articles favorable to its hormone replacement therapy Prempro, according to Congressional letters seeking more information about the company's involvement in medical ghostwriting.

The documents show company executives came up with ideas for medical journal articles, titled them, drafted outlines, paid writers to draft the manuscripts, recruited academic authors and identified publications to run the articles — all without disclosing the companies' roles to journal editors or readers.

The issue of ghostwriting for medical journals has been raised in the past, involving various companies and drugs, including the Merck painkiller Vioxx, which was withdrawn in 2004 after it was linked to heart problems, and Wyeth's diet pills, Redux and Pondimin, withdrawn in 1997 after being linked to heart and lung problems.

Wyeth Pharmaceuticals and Pharmacia & Upjohn Co. are now divisions of Phizer Inc.

There are some 10,000 Prempro cases currently in litigation by various attorneys across the United States. In the news recently have been several jury awards against Phizer in cases where Wyeth's Prempro caused breast cancer. Although the United States Court of Appeals for the Eighth Circuit overturned one such award, the judges' ruling said, "There was sufficient evidence upon which a jury could conclude that Wyeth acted with reckless disregard to the risk of injury."

If you have been diagnosed with breast cancer, heart disease, stroke or blood clots and have taken Prempro for Hormone Replacement Therapy, you may be entitled to compensation. Call Napoli Bern Ripka, LLP today at 888-529-4669 to discuss your legal options.