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VERDICT

A Publication of the Mass Tort / Personal Injury Law Firm of Napoli Bern Ripka LLP

WARNING

Do Your Prescription Drugs Have Dangerous Side Effects?

The following pages detail recent drug product liability lawsuits currently being handled by Napoli Bern Ripka LLP:

- Antibiotic - Levaquin[®]
- Birth Control Pill - Yasmin[®]
- Birth Control Pill - Yaz[®]
- Hip Implant Prosthesis - Zimmer Durom Cup
- GERD (Reflux) - Reglan[®]

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We Can Handle Your Lawsuit for the Antibiotic **Levaquin**[®]

Levaquin[®] is an antibiotic that is manufactured by Ortho-McNeil[®], which is a subsidiary of Johnson & Johnson. This medication is used to prevent bacteria from reproducing and causing infections.

Levaquin is part of a group of antibiotics known as fluoroquinolones. One of the major side effects that have resulted from the use of Levaquin, as well as another major antibiotic, Cipro, has to do with ruptured tendons.

Ruptured Achilles tendons as well as ruptures in the tendons of the shoulders and hands have been attributed to the use of Levaquin. Because there have been no warnings alerting patients of the potential dangers associated with these antibiotics, a consumer advocacy group filed a lawsuit in January of 2008. They were moved into action because of the FDA's failure to require the makers of these antibiotics to include warning labels on their products. More specifically, the call for information about the risk of tendon ruptures from using Levaquin.

By July 2008, the Food and Drug Administration required makers of the fluoroquinolone antibiotics to include the most serious of FDA warnings, the black box warning on all of their packaging labels. The prominent label had to alert users of the risk of tendon rupture and tendonitis.

In addition to the black box warning, the FDA required the companies to include a Medication Guide that explained in detail about the risks involved and urged users to contact their doctors in the event they contracted a ruptured tendon.

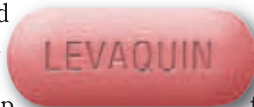
There are a number of individual as well as class action suits against Levaquin being filed every day as a result of the company's failure to provide adequate warning prior to using these antibiotics.

While ruptured tendons are not a life-threatening situation, they are indeed a serious and painful side effect that you shouldn't have to suffer from just to treat a bacterial infection. The pain and

discomfort associated with ruptured tendons can actually escalate to the point where the patient has trouble of can't walk, especially when it affects the Achilles tendons.

If you, someone in your family or anyone you know has used the fluoroquinolones antibiotic Levaquin or even Cipro, and suffered from ruptured tendons or a ruptured Achilles tendon as a result of using either of these medications please contact us here at Napoli Bern Ripka Law Firm. We will provide you with information to help you determine the best avenue to take in seeking compensation for your suffering.

If you live in New York you can make an appointment to come to our office, which is located in the Empire State building. We also have offices throughout the country. We are committed to helping our clients realize the justice that they deserve. ●



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 you 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. ●

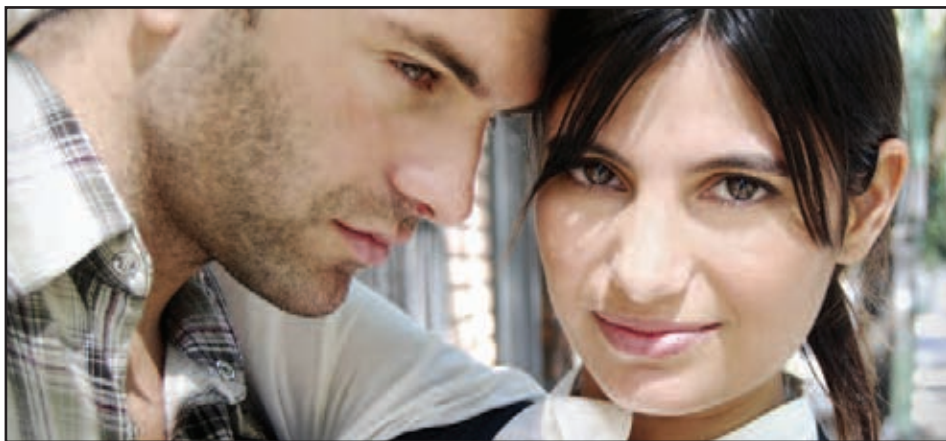


Serious Injury and Death Associated with Birth Control Pill Yaz[®]

Yaz[®] is the brand name for a relatively new birth control pill that is a combination of progestin hormones (drospirenone/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 FDA did not approve Yaz for use with these symptoms.

In February of this year, the US 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 pharmaceutical company is required to invest \$20 million to make new commercials. The new

settlement requires that the new television commercials be submitted to the FDA for approval prior to being aired. This is an unusual demand that the FDA is making. Normally, this step is voluntary.

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. Because of these symptoms and injuries, a large number of lawsuits are being filed in behalf of the victims to the extent that attorneys across the country are dotting this event the newest mass tort.

If you or someone you know is taking the prescription medication Yaz that is manufactured by Bayer Healthcare and have had any of the symptoms or side effects associated with this drug, you may be entitled to compensation. Contact the professional attorneys at Napoli Bern Ripka Law Firm by calling toll free 1-888-529-4669. ●

Lawsuits Regarding Implanted Hip Prosthetic

Zimmer Durom Cup

The Zimmer Durom Cup is an artificial hip component that has been used in hip replacement surgeries in the US since 2006. It is different from other hip replacement components in that it is made from a single piece of material. However, in April of 2008, Dr. Larry Dorr, an orthopedic surgeon from Los Angeles notified members the American Association of Hip and Knee Surgeons that some of his patients who had received the Zimmer Durom Cup implant were having problems with it.

His patients had informed him that they were suffering from unexplained pain in their hip area a good three months after surgery. They also felt a loosening of the hip implant. Their conditions required revision surgeries to correct the problems and Dr. Dorr felt that the number of patients that needed a second surgery to correct the problems associated with the implant were higher than should be expected.

Initially, Zimmer Holdings, Inc. dismissed the reports that they were receiving from doctors about problems with the implant. But, in May of 2008, Zimmer decided to conduct an investigation into the Durom Cup problems. Information from over 3,100

cases was carefully reviewed and as a result, Zimmer basically concluded that the average orthopedic surgeon was not trained well enough in the use of this device to handle the surgery.

The company felt that the design of their implant and the technology associated with it required a very high degree of precision and skill during a hip replacement surgery that included the use of their implant. They felt that this specialized technique was not normally a part of the doctor's procedures in hip replacement surgery. Zimmer decided that orthopedic surgeons needed special training and instructions before they operated using the device.

So, in July of 2008, Zimmer suspended sales of the Durom Cup device in the US, but they did not issue a recall. This was because the company's investigation did not find any evidence of defect in the design or manufacturing process of their product. Instead, the company plans to reintroduce the artificial hip implant into the market after they complete the development of a specialized training course, complete with detailed instructions concerning the specific surgical technique that doctors need to follow in order to avoid problems with the implant.

Some 12,000 people in the US have had hip replacement surgery by doctors that used a Zimmer Durom Cup. Many have complained of problems with it and many more could suffer issues with the implant in the future and may need revision surgeries. Zimmer Holdings, Inc. neglected to provide an advanced warning that special training and instructions were needed before their product was implanted. They also failed to provide those instructions before introducing the product into the market.

If you or someone you care about has suffered problems with the Zimmer Durom Cup implant or has had to undergo revision surgery to correct the problem, you may be eligible for compensation. Let the professional team of lawyers at Napoli Bern Ripka Law Firm fight for your rights. ●





Lawsuit Associated
with Side Effects of
Reglan®
Prescribed for GERD

Reglan® is a product that was manufactured by Wyeth and Schwarz Pharmaceuticals to treat acid reflux or gastro esophageal reflux (GERD), heartburn, nausea and vomiting. It was distributed by Baxter Healthcare and was approved by the FDA in 1985. More than two million prescriptions for Reglan have been administered since the product hit the market. The company enjoys over \$27 million in profits each year from sales of this product.

Reglan, or metoclopramide, is a dopamine inhibitor and its purpose is to strengthen the muscles of the stomach as it goes through the digestive process. In order to prevent acid reflux Reglan helps move the process on a little more rapidly.

But the side effects of this product began to show up fairly quickly. While reducing the levels of dopamine the hormone prolactin was activated and

began to affect the central nervous system. Patients who took Reglan began experiencing side effects that were similar to those of Parkinson's patients as they were unable to control the movement of their bodies. Symptoms even began mimicking the effects of Tardive Dyskinesia with twitching, involuntary shaking and tremors and extreme facial movements.

And if that weren't enough, symptoms of Reglan produced suicidal thoughts and attempts, loss of sexual desire in women and erectile dysfunction in men. Patients also suffered from depression, memory loss and confusion and extreme anxiety.

By February of 2009, the Food and Drug Administration stepped in and required Wyeth and Schwarz to include warning boxes on their product alerting people to the dangers associated with taking this medication. Originally the FDA had approved Reglan for patients who could not find any other relief for their acid reflux problems. But the drug was only deemed safe in low doses and for short periods of time. Major concerns began as the number of people who developed Tardive Dyskinesia increased after using Reglan.

The side effects of taking this medication seem to persist even after you stop taking it. Patients who took Reglan in higher doses for periods of 3 months or longer showed signs of the seizures and muscle movements listed above and in a lot of cases the effects were permanent.

If you, someone in your family or anyone you know used the drug Reglan to

resolve acid reflux issues and suffered any of the side effects listed here, please contact us here at Napoli Bern Ripka Law Firm. You may be eligible for compensation through any number of class action suits against the makers of this drug.

If you live in New York you can make an appointment to come to our office, which is located in the Empire State building. We also have offices throughout the country. We are committed to helping our clients realize the justice that they deserve. We have recovered over a billion dollars for our clients. Let us put our expertise to work for you. ●



Napoli Bern Ripka LLP
Attorneys at Law

Napoli Bern Ripka LLP is ready to fight for your rights in the following areas:

- Securities Arbitration
- Medical Malpractice
- Personal Injury
- Accidents
- Labor Law
- FDA and Prescription Drugs
- Product Liability
- Wrongful Death
- Environmental Litigation

We are ready to stand by your side to get you the justice — the VERDICT — you deserve.



For More Information

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