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THE MANN MAINLINE

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Dangerous Drugs & Defective Products: We're Here to Help

In an effort to serve you, our clients, the best way we know how, we have decided to expand our practice to include Dangerous Drugs and Defective Products. It is important to know that there is "strength in numbers" when dealing with big corporations. Because so many of cases involve the same products and companies, we can handle a large number of these cases at a lower cost to each client. And because we have a staff that works as a team, you get the individual attention you deserve. In some cases, we work in cooperation with other law firms to better serve our clients. This combination of large-scale effort and personal attention is designed to maximize your recovery and to keep you well informed. Our goal with this newsletter is to introduce you to this new practice area. Therefore this entire edition is dedicated to informing you about various drugs and their possible effects on you. Going forward, however, each newsletter will contain a new drug or defective (recalled) product that we feel you should be aware of. As you read these newsletters or review our website, please don't hesitate to contact the firm if you believe you or a loved one have experienced one of the serious side effects mentioned.

We are here to help: 478-742-3381 or www.manninjurylaw.com.

Be Careful with Sugar Intake

A spoonful of sugar may, as Mary Poppins sang, help the medicine go down. But too many spoonfuls will probably increase your need to take medicine in the first place.

Too much sugar—or rather, the unproductive calories it delivers to the body—can lead to weight gain, diabetes, and heart disease, among other health problems.

How much is too much?

An American Heart Association study found that Americans consume an average of 22 teaspoons a day (at least during the period of 2001-2004). AHA guidelines recommend much less: six teaspoons a day for women, and nine teaspoons for men.

Check the labels of the foods you're eating: a lot of sugar can be founded in most processed foods. And don't rely on sugar substitutes like high-fructose corn syrup. Though fructose may have less impact on the body's blood sugar and insulin levels, a calorie of fructose has the same impact as a calorie of sugar. As in most things, moderation is key.

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Find Us On:

Eliminate Your Excuses for Skipping the Gym and Get on Pace of a Healthy New Year!

Regular exercise is an important part of maintaining your health. Going to the gym once a month won't do it, no matter how hard you work out that day. When you're busy, or tired, or bored, skipping your workout can sound attractive. Here's how to fight the temptation to avoid exercise when you're not in the mood:

- **Redefine "exercise."** You don't have to spend hours at the health club to stay in shape. Keep track of your daily activity and try to incorporate healthy behaviors like walking for at least 20 minutes, taking the stairs instead of the elevator, or getting off the bus or train a block early. Exercise will become part of your day, not an added chore.
- **Clear your mind.** Make a regular date with yourself for exercise and train yourself not to think about all the other tasks you could be doing. Focus on the here and now and don't get distracted by the future or the past.
- **Find exercise you enjoy.** Most gyms offer a variety of exercise equipment, so choose an activity that makes you feel good while you're doing it, not something you detest no matter how beneficial it may be. Riding a bike through your neighborhood is just as helpful as sitting on a stationary bicycle in the gym.
- **Set your own goals.** Even if you work with a buddy or trainer, decide for yourself what you want to achieve. Set realistic targets that challenge you, not impossible goals that make you reluctant to try.
- **Shorten the duration.** Rather than a single hour long session, aim for three 20-minute workouts or four 15-minute workouts a day. People who opt for shorter sessions actually tend to work out more over the course of a week.
- **Pick a partner.** People who exercise with friend have a higher success rate.

If you set goals and set-up a plan you are much more likely to succeed. You owe it to yourself and your loved ones to get on pace for a healthy new year and a healthy life!

Cymbalta

Cymbalta is a popular antidepressant that helps control neurotransmitters and hormones, improving moods and alleviating pain. Eli Lilly is the manufacture of this multi-use drug, which originally received FDA approval for alleviating mental and physical discomfort.

In 2004, the FDA also approved Cymbalta to treat depression. Doctors soon began prescribing Cymbalta for a wide range of patients, including those with anxiety, diabetic neuropathy, muscle pain and stress urinary incontinence. In 2007, the FDA added the treatment of fibromyalgia - a type of arthritis characterized by muscle pain, trouble sleeping, and tiredness.

Unfortunately, patients wishing to discontinue use of the drug often suffer from side effects that impair their health, some that can last weeks after stopping the Cymbalta treatment. These withdrawal symptoms range from minor side effects like headaches and dizziness to very serios ones like suicidal ideation and blackouts.

Like Effexor, Cymbalta works as a serotonin-norepinephrine reuptake inhibitor (SNRI). The SNRI drug class deals with norepinephrine and aims to improve energy levels. Similar to SSRIs, Cymbalta also deals with serotonin levels, which can often lift moods.

The FDA initially approved the drug for treating depression, and within a year approved it for diabetic neuropathy. For diabetic neuropathy, Cymbalta treats pain and tingling from nerve damage. As noted above, generalized anxiety disorder, which is a condition that more than 6 million Americans suffer from every year, was added to the list of possible conditions it would treat.

Within five years of the drug hitting the market, doctors prescribed 2.8 million patients Cymbalta, according to an FDA report. Of these prescriptions, 400,000 were prescribed for "off-label" uses like nerve pain, musculoskeletal pain and headaches. In 2008, the FDA approved its use for Fibromyalgia.

Patients taking Cymbalta are often unaware of the potential side effects that may occur, and doctors continue to prescribe it for more uses despite these dangers. Below are some possible complications of discontinuation:

- Dizziness
- Weight Gain
- Anger
- Burning Sensation
- Suicidal Thoughts
- Persistent Withdrawal Symptoms/Brain Zaps

An Institute of Safe Medication Practices (ISMP) published report described 48 instances where Cymbalta users suffered from debilitating withdrawal side effects, including brain zaps.

While a brain zap/persistent withdrawal symptoms is not a precise medical term, many Cymbalta users have experienced the same type of abrupt electrical shock disrupting their mind. They describe the zaps as intense and painful sensations that cloud mental clarity and leave them with shakes, nausea and headaches. The degree of severity can impair a patient's ability to work, socialize and carry out daily tasks.

Even with abrupt discontinuation of the drug similar symptoms occurred in nearly half of patients. And, of those, at least 10 percent felt symptoms acutely and half continued to suffer from side effects more than one to two weeks after stopping treatment.

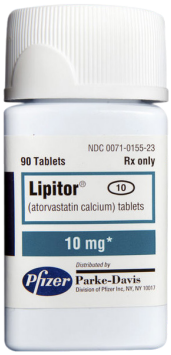
Many of these patients required hospitalization and also reported nausea, tremors and blackouts. It was noted that communications from the FDA and Eli Lilly to the public, regarding these safety concerns, were insufficient.

The United States, along with many other countries have added numerous warnings to Cymbalta. In 2005, the FDA censured Eli Lilly regarding "professional journal ads" that contained misleading information about Cymbalta. It sent a letter to Eli Lilly describing the misleading portion of ads as failing to disclose important risks and side effects. The ads have been discontinued. But, this does nothing to halt the dangers. The reported warnings concern the following:

- Suicidal thoughts and behaviors
- Serotonin syndrome
- Aggression
- Birth defects
- Death

People struggling with severe withdrawal symptoms related to Cymbalta use may possibly take action and file lawsuits against the drug's manufacturer for not properly warning users of the drug's danger.

Lipitor



Lipitor is manufactured by Pfizer pharmaceuticals as a cholesterol-lowering drug. Lipitor prevents heart attack and stroke by lowering cholesterol in the blood. Cholesterol plays a crucial role in several bodily processes that are essential to our health, but unhealthy levels of cholesterol can lead to serious health complications. Lipitor is the most popular of all statins, which represent the most widely-prescribed class of drugs in the United States. Patients take statins to lower levels of cholesterol and other fatty substances in the blood that, if left unchecked, can increase the risk for heart attack, stroke and other related health complications. Lipitor was approved by the FDA in 1996.

While Lipitor has been proven to significantly reduce the potentially life-threatening risk for cardiovascular disease faced by some patients, the statin class of medications has been associated with multiple serious side effects, including an increased risk of type 2 diabetes.

Doctors commonly prescribe Lipitor to help stave off cardiovascular disease in patients who may develop heart conditions. The drug can be used to reduce the risk of heart attack, stroke and chest pain for patients with multiple heart disease risk factors, including advanced age, a family history of cardiovascular disease, low levels of good cholesterol (HDL) and a history of smoking or hypertension. Patients already diagnosed with heart disease also take the drug to lower their risk of having a cardiac event.

Approximately 20 years after Lipitor was first approved, evidence of a diabetes risk from statins first appeared. Data collected from 91,000 patients treated with either a statin or a placebo revealed that 0.4 percent of statin users went on to developed diabetes, but researchers later found this figure to be inaccurate. Further studies revealed that some statins pose a higher risk for new-onset diabetes, particularly those commonly prescribed in higher potencies like Lipitor, Zocor and Crestor.

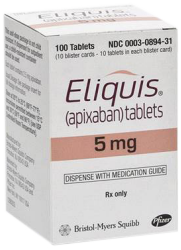
Among more than 470,000 patients newly treated with a statin, researchers found that the drug class is associated with a 10 to 22 percent increased risk for type 2 diabetes. Lipitor and Crestor presented the highest diabetes risk at 22 and 18 percent, respectively. Additional studies indicate that diabetes risk is higher for certain groups, including the elderly, women and Asians.

In a February 2012 consumer update, the FDA communicated several new health complications associated with Lipitor use, including an increased risk for high blood sugar (hyperglycemia) and the development of type 2 diabetes. In addition, the results of a 2012 study published in the Archives of Internal Medicine found that the diabetes risk of Lipitor and other statins is significantly pronounced among post-menopausal women.

Although the FDA approved Lipitor in 1996, Pfizer failed to communicate the drug's link to high blood sugar and increased risk for diabetes until February 2012. Nearly six months earlier, at the request of the FDA's Division of Metabolism and Endocrinology Products, Pfizer finally agreed to update Lipitor's labeling to indicate these risks.

Hundreds of Lipitor users who later developed type 2 diabetes filed legal claims against Pfizer, alleging that their illness was a direct result of treatment. They claim the drug maker knew about or should have known about the diabetes risks of Lipitor before marketing it as a safe and effective treatment. These plaintiffs seek compensation from Pfizer, accusing the drug maker of neglecting to adequately warn patients and doctors of the full range of Lipitor's health risks.

Eliquis and Xarelto



As many of you know from direct-to-consumer advertising on television, there is a new class of blood thinners, which are publicized as being safer and more convenient than Coumadin or Warfarin. **Among the blood thinners in this new drug class are Eliquis and Xarelto.**

But there is one fact that is given less attention in those TV ads: To this point in time there is no way to quickly restore normal clotting for patients in need of emergency surgery or to stop a major bleeding episode while on Eliquis and Xarelto.

A few recent articles address this fact from the perspective of medical doctors who might prescribe Eliquis and Xarelto as well as emergency room doctors who may have to treat patients on these newer anticoagulant medicines. From this December 23, 2015 Reuters news report, "New blood thinner 'antidote' to help doctors move past warfarin", we get some insight about this current "no antidote" situation:

Xarelto, from Bayer AG and Johnson & Johnson, and Eliquis, sold by Bristol-Myers Squibb and Pfizer, were approved as safer and more convenient alternatives for preventing blood clots and strokes than Warfarin. But there is one very important issue: there is no way to quickly restore normal clotting for patients in need of emergency surgery or to stop a major bleeding episode, leading many doctors to hold off on prescribing the drugs.

Major bleeding events may not generally be common, but unfortunately when they do occur they are severe. There is no specific protocol for reversing these drugs. This leaves most doctors feeling a little uncomfortable about prescribing them at all. Many physicians, particularly surgeons, hate these drugs. This is due to the fact that they have to deal with the consequences of somebody coming in with trauma, while using the new blood thinners.

Although these new drugs represent an important advance in anticoagulation therapy, concern over the lack of antidotes has tempered enthusiasm for their use among both patients and physicians because of the perception of better safety with Warfarin as a result of the availability of effective reversal strategies.

Client's Bill of Rights

Lawyers will tell you that it is impossible to offer a guarantee in the legal business. WRONG! We say that law firm clients should settle for nothing less! Remember, your attorney works for you – not the other way around.

At Mann Law we believe we can promise our clients quality service with personal attention. We believe that as our client you are entitled to have the:

1. Right to loyalty to you and your cause.
2. Right to be updated regularly and in a timely manner as to the progress of your case.
3. Right to our respect.
4. Right to expect competence from our firm and all who work here.
5. Right to know the truth about your case.
6. Right to prompt attention from us.
7. Right to have your legal rights and options explained in plain English without legal mumbo jumbo.
8. Right to a fair written fee agreement with our firm.
9. Right to a fair fee for the work we do.
10. Right to make the ultimate decision on your case.

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Actos

Actos is an oral Type 2 diabetes drug.

- Allows the body to better dispose of excess blood sugar.
- Makes the body's cells more sensitive to insulin.
- Can be used alone or with other Type 2 diabetes medicines like metformin.
- Decreases insulin resistance and decreases the glucose made in the liver

Approved by the U.S. Food and Drug Administration (FDA) in 1999, the type 2 diabetes drug Actos, along with diet and exercise, helps control blood sugar. But, it is also a controversial drug that is linked to a number of serious side effects, including congestive heart failure, kidney disease and bladder cancer.

Eli Lilly partnered with Takeda to market the drug, and it became one of the most successful diabetes medications of all time. Before the manufacturer lost the patent on Actos in 2011, its U.S. sales were $3.58 billion in 2010. But, it is a possible side effect unique to Actos that now raises concern: bladder cancer. In August 2011, the FDA required that Takeda update the drug's Warnings and Precautions section of the label to include a warning that use of the drug for over a year may be associated with an increased risk of bladder cancer.

The latest study on Actos was published in May 2012. This study revealed that people who take Actos for an extended period have an 83 percent higher risk of developing bladder cancer. Before 2012, a few studies – including Takeda's own preclinical trials – already linked the drug to bladder problems. According to the FDA, researchers noted a higher incidence of bladder cancer in patients who took Actos versus those who took other drugs. As a result of these studies, the FDA required that Takeda undertake a 10-year study of the drug's link to bladder cancer. Symptoms of bladder cancer include the following:

- Bloody Urine
- Pain when urinating
- Increased urge to urinate
- Unusual back pain

Thousands of people who took the drug filed lawsuits against Takeda Pharmaceuticals and Elli Lilly after doctors diagnosed them with bladder cancer. Takeda in April 2015 agreed to settle thousands of Actos bladder cancer claims for at least $2.37 billion in one of the largest pharmaceutical settlements in U.S. mass torts history. The record Actos settlement covered about 9,000 cases, meaning about $275,000 for those who sign into the settlement, which outlines guidelines to qualify for compensation. The cost of the agreement rose to $2.4 billion when at least 97 percent of cases opted to settle in September 2015.