

TAYLOR MARTINO PHARMACEUTICAL & MEDICAL DEVICE LITIGATION

HORMONE REPLACEMENT THERAPY

PREMPRO (Estrogen/Progesterone Combination)

- Prempro is a hormone replacement therapy (HRT) introduced by Wyeth Pharmaceuticals in 1996. It is used to treat hot flashes and other symptoms of menopause. At HRT's peak, an estimated 15 million women were on hormone replacement therapy. However, no one had conducted a large clinical trial to test its use.
- We are currently evaluating cases involving women who developed breast cancer.

ESTRATEST (Esrogen/Methyltestosterone Combination)

- Estratest is a hormone pill made up of both estrogen and testosterone. It is manufactured by Solvay Pharmaceuticals in Marietta, Georgia. Estratest has been sold, marketed and promoted as an effective treatment of vasomotor symptoms "hot flashes" related to menopause. It has been promoted, marketed and sold for this use since 1964. Interestingly, Estratest has never been approved by the FDA.
- According to the WHI study, a study of over 70,000 nurses, Estratest doubles the risk of breast cancer in women. The study's conclusions, published in the July 24, 2006 Archives of Internal Medicine journal adds to the data that certain types of hormone supplements (estrogen-progestin pills), increase women's threat of breast cancer, heart attacks and strokes.
- We are currently evaluating cases involving women who developed breast cancer.

KUGEL MESH HERNIA PATCH

- A mesh insert used in hernia repair surgery to repair abdominal hernia defect. This patch has caused serious injury in patients due to a defective recoil ring in the mesh. Bowel perforation, sepsis, infection, scarring and disfigurement have occurred as a result of the defect in this device.

DURAGESIC PATCHES

- Approved by the U.S. Food and Drug Administration (FDA) in 1990, the Duragesic patch releases fentanyl, a strong opioid, through the skin at a fixed rate for 72 hours. The patch is recommended for patients who are already on and tolerant to opioid therapy, and require continuous opioid administration.
- Duragesic patches have been subject to a recall due to the medication leaking from the patch as a result of improper sealing of their edges. If the medication leaks out of the patch, exposure to the medication can result in inadvertent ingestion or increased transdermal absorption of the active opiate component fentanyl, leading to potentially

life-threatening complications. In addition, leakage of the medication could lead to inadequate dosing, resulting in treatment failure and/or opiate withdrawal.

- Janssen Pharmaceutica, the manufacturer of the Duragesic Patch notified healthcare professionals of an expanded recall of the Duragesic 75 mcg/h, in February 2004. On July 15, 2005 the FDA issued a Public Health Advisory concerning the use of Duragesic Patches (Fentanyl transdermal) in response to reports of deaths in patients using the patch.
- We are currently conducting an investigation into deaths associated with these patches.

MEDTRONIC SPRINT LEADS

- The Sprint Fidelis lead has been used in implantable Medtronic defibrillators since 2004, and most patients who received the devices since then have the faulty leads. On October 15, 2007, Medtronic announced that it was suspending sales of the Sprint Fidelis lead, a vital component in its implantable defibrillators. According to Medtronic, the Sprint Fidelis lead, a wire that connects the Medtronic defibrillator to the heart, could fracture inside a patient's blood vessel, delivering a massive electrical jolt. This malfunction can cause extreme pain, or in the worse case scenario, it can be fatal. At least 5 deaths have already been linked to a malfunctioning Sprint Fidelis lead used with an implantable Medtronic defibrillator.
- According to recent surveys, many patients who have been implanted with heart devices are not aware of recent recalls and do not understand the dangers they might face. There are fundamental problems with even the physician's understanding of the situation and an appropriate focus on accurate information. nearly one in five heart patients didn't know about recent recalls of their devices

GADOLINIUM

- Gadolinium, which is pronounced gad•o•lin•i•um, is a chemical element in the periodic table used in an MRI/MRA in order to better observe lesions with abnormal vascularity (or those thought to cause abnormalities in the blood-brain barrier) in the brain (intracranial lesions), spine, and associated tissues.
- Gadolinium was endorsed for use in MRI scans in 1988 and has been used in millions of studies since. Gadolinium side effects have been known to cause Nephrogenic Systemic Fibrosis (NSF) a disorder characterized by widespread tissue fibrosis. Many people don't know what gadolinium is or why they should be concerned.
- In December of 2006, the FDA issued its second public health advisory regarding gadolinium based contrast dyes. At that time, the FDA said it had received 90 reports of patients with moderate to end-stage kidney disease who developed NSF after being exposed to gadolinium based contrast agents. At the time of this alert, the FDA said about 215 patients worldwide were known to have NSF. Of those whose medical history were known, all had been exposed to gadolinium contrast agents prior to diagnosis.
- In May 2007, the FDA requested that the manufacturers of the five gadolinium based contrast agents used in MRIs include a boxed warning – the FDA's strongest possible safety warning – on product labels highlighting the risk they posed to patients with kidney problems. The FDA warned that patients who are at risk for NSF should be

monitored by their doctors, and told to report any symptoms associated with the condition immediately. The FDA has also set up a reporting program so that healthcare providers can report instances of NFS caused by Gadolinium based contrast agents.

PAXIL/SSRI BIRTH DEFECTS

- Paxil is part of a class of antidepressants called selective serotonin reuptake inhibitors (SSRIs). SSRIs affect serotonin levels in the brain, a chemical neurotransmitter. Serotonin is produced in the brain on an ongoing basis and in response to pleasure-giving experiences, in a normally healthy system.
- Paxil - known generically as paroxetine - was brought to market by GlaxoSmithKline in 1992, and by 2006, Paxil was the fifth most-commonly prescribed antidepressant in the US, with more than 19.7 million prescriptions. Paxil was approved by the FDA to treat symptoms of depression, obsessive-compulsive disorder (OCD), post-traumatic stress disorder (PTSD), panic disorder, generalized anxiety disorder (GAD), social phobia/social anxiety disorder, and premenstrual dysphoric disorder (PMDD). Paxil was the first antidepressant formally approved in the US for the treatment of social anxiety disorder.
- In September 2005, the FDA and GlaxoSmithKline alerted doctors about a new study on major birth defects seen in babies born to women who took the antidepressant Paxil during the first trimester of pregnancy. The alert was based on a study GlaxoSmithKline conducted of major birth defects in infants born to women who took antidepressants. In December 2005, the FDA announced that it was requiring GlaxoSmithKline to add additional warnings about Paxil birth defects to the drug's prescribing information. The FDA took the action because the early results of two more studies showed that women who took Paxil during the first three months of pregnancy were about one and a half to two times as likely to have a baby with a heart defect as women who received other antidepressants or women in the general population.g Paxil - during the first trimester of pregnancy.
- We are currently investigating cases of children who have suffered Paxil and SSRI birth defects.

ORTHO EVRA

- In 2005, the FDA stated that women using Ortho Evra are exposed to approximately 60 percent more estrogen than those who use oral contraceptive pills. It is believed that the difference in exposure is related to the delivery mechanism of the birth control patch. Hormones in birth control pills are partially diluted by the digestive system. However, hormones in Ortho Evra are absorbed directly into the blood stream, which causes a higher concentration of the medication to enter a patient's body. It is believed that high levels of estrogen can greatly increase the risk of developing blood clots, heart attacks, strokes and other serious injuries.
- On September 20, 2006, results of a new study were released that confirmed previous studies showing an increased risk of blood clots associated with the use of Ortho Evra versus oral contraceptives. The study found that women using Ortho Evra were twice as likely to develop blood clots as those using oral contraceptive pills. As a result, the FDA has asked Ortho McNeil Pharmaceuticals, a division of Johnson & Johnson, to update the safety label on Ortho Evra to warn users about the risk of blood clots, heart attacks and strokes
- Approximately 4 million women have used the Ortho Evra Patch since it went on sale in 2002. As of November 2005, the FDA had received twenty-one reports of life-threatening blood clots and other ailments associated with the use of Ortho Evra. FDA records obtained by the Associated Press showed that seventeen patch users between the ages of 17 and 30 suffered fatal heart attacks, blood clots and possible strokes since August 2002.
- The first fatality publicly blamed on the Ortho Evra patch was in April 2005, when a Manhattan fashion student collapsed in a New York City subway station. An autopsy found that a blood clot had moved into the victim's lung, and the medical examiner ruled that the clot was a side effect of Ortho Evra.
- The manufacturers of Ortho Evra have aggressively marketed the patch as a convenient alternative to oral birth control pills. The drug's original safety label stated that the patch's health risks were similar to those related to oral contraceptives, even though a recent whistleblower suit alleges that the company was well aware that the birth control patch could cause high rates of blood clots.

FOSAMAX

- Fosamax, a popular osteoporosis drug, has been linked to severe musculoskeletal pain (pain of the joints, muscles, and/or bones), as well as a serious bone disease called Osteonecrosis of the Jaw (ONJ), also known as "dead jaw" and "fossy jaw". An article on the association between Fosamax and ONJ was first published in the *Journal of Oral and Maxillofacial Surgeons*, which prompted the US Food and Drug Administration (FDA) to review the safety of Fosamax and other drugs in its class (bisphosphonate drugs). On January 31, 2005, Merck, the manufacturer of Fosamax, received a request for data from the FDA to update the label for Fosamax to include labeling for the jawbone tissue disease. The revised label was not made available until July 2005
- On January 7, 2008, the FDA warned that Fosamax had been linked to severe and sometimes incapacitating bone, joint, and muscle (musculoskeletal) pain. The agency advised doctors and patients to be aware of this side effect, and to discontinue Fosamax use should it occur.
- It is thought that Biofilms, a mix of bacteria and sticky extracellular material, are the cause of jaw tissue infections in patients taking bisphosphonate drugs like Fosamax, Actonel and Boniva

FLUROQUINOLONES (Levaquin, Cipro, Tequin)

- Levaquin is a member of the quinolone family of antibiotics and is prescribed to treat bacterial infections affecting the lungs, urinary tract and skin. Levaquin is available by prescription only and is manufactured by Ortho-McNeil Pharmaceuticals. Levaquin was approved by the U.S. Food and Drug Administration (FDA) in 1996. The drug has been linked to peripheral neuropathy and tendon ruptures. The most common ruptures associated with Levaquin usage are those to the Achilles and the shoulder.
- Cipro, Levaquin, Tequin and other antibiotics known as fluoroquinolones have long been known to cause serious side effect, including tendon damage. Yet despite massive amounts of evidence, the Food & Drug Administration (FDA) has not required the makers of fluoroquinolone antibiotics to add warning labels about their links to ruptured tendons and other tendon problems.

POWDERED INFANT FORMULA

- A recent study concluded that powdered infant formula can cause serious illness or death in infants. The infants are typically diagnosed with Meningitis, Salmonella, Sepsis or Bacteraemia. These illnesses can often lead to brain damage or death. Powdered infant formula can be contaminated with harmful bacteria during the manufacturing process or contaminated if not handled properly. Doctors often diagnose the illness as Meningitis, Salmonella, Sepsis, or Bacteraemia. These illness can be caused by the bacteria *E. Sakazakii*.
- Over the past 40 years there have only been 50 reported cases of people affected with *E. Sakazakii*, but there is evidence to suggest that many cases go unreported. Most of the reported cases have been infants with the death rate being between 33% and 50% in infants. Infants that do survive usually suffer permanent brain damage.

- E. Sakazakii can be found in the environment, but scientific studies have linked the infection in infants to powder infant formulas. Powder Infant Formulas are not sterile and can become contaminated with high amounts of E. Sakazakii during the manufacturing process, or by improper preparation, dilution, storage, or hygiene.
- Research has concluded that infants most at risk for becoming infected are those with Low birth weights or less than two months old. This condition also suggest that infected infants may be lacking sufficient colonization of the gastrointestinal tract with normal bacterial flora to compete with the opportunistic pathogen, E. sakazakii. Similarly, in the adult cases, most had underlying diseases that could have increased their chances of being infected with E. sakazakii.
- Infants that are infected by E. sakazakii show the following symptoms: poor feeding response, irritability, jaundice, grunting respirations, and instability of body temperature. As the infection progress infants will being to suffer from severe neurological impairment, Ventriculitis, brain cysts and abscesses, cerebral infarction, and hydrocephalus.