



Alley & Ingram
 701 E. Washington Street
 Tampa, FL 33602
 (813) 222-0977
 (813) 224-0373 Fax

PRST STD
 U.S. POSTAGE
PAID
 TAMPA FL
 PERMIT 3024



Hearsay

Arthritis Drugs Under Fire



For years, scientists have expressed concerns about the safety and effectiveness of Vioxx, Celebrex and Bextra. These drugs are known as Cox II inhibitors and were marketed as “super aspirin.” The drugs work by blocking the Cox II enzyme which is associated with inflammation in the body. Traditional anti-inflammatories, such as Aleve and Naproxen, block both Cox I and Cox II enzymes. However, researchers working on the development of these drugs noted that there is a very fine balance that must be maintained with Cox I and Cox II enzymes, and that blocking only Cox II causes the body to form clots. These clots in turn lead to heart attacks, strokes, and pulmonary emboli from deep vein thrombosis. At one point, Merck, the manufacturer of Vioxx, considered adding aspirin to the Vioxx formulation to avoid this clotting problem, but ultimately decided that such an admission would likely “kill the drug.” When Vioxx was recalled, Merck led the public and physicians to believe that the health risks had just been discovered. However, the potential of Vioxx to cause blood clots resulting in heart attacks and strokes was known to the company before the drug was ever marketed, and has been noted in several studies conducted by those outside of Merck as early as 2000. Unfortunately, most physicians were unaware or did not heed these warnings, largely due to the aggressive marketing efforts by Merck to downplay these risks when selling to physicians. An Advisory Committee will be meeting soon to determine whether Celebrex and Bextra will be permitted to remain on the market. If you have taken Vioxx, Celebrex or Bextra and sustained a serious injury such as a heart attack, stroke, or blood clot, please contact **Alley & Ingram** for more information about your legal rights.

Alley & Ingram

Attorneys At Law

701 East Washington Street • Tampa, FL 33602
 (800) 840-0977 or (813) 222-0977 • Se Habla Español



Representing Plaintiffs Exclusively in the Following Cases:

- Medical Malpractice
- Nursing Home
- Automobile Accidents
- Products Liability
- Insurance Disputes
- Drugs & Medical Devices

ARTHRITIS DRUG SAFETY RISKS



Litigation Updates for Pharmaceutical Clients



*A*lley & Ingram has been extremely busy over the past few months. We are currently preparing for upcoming Vioxx, hormone replacement and diet drug trials. Below are updates on ongoing projects:

BREAST IMPLANT CLAIMS We are starting to receive settlement payments on behalf of our clients who were implanted with Dow Corning breast implants (Class 5 claimants). Most of the payments are explant payments. Nearly all of our claims were submitted in advance of the June 1, 2004, official opening of the Claims Facility. As such, they are at the head of the line, as most claims were not submitted until the last half of 2004. The Claims Facility has certainly gone through some growing pains but hopefully will be able to increase the volume of claims processed shortly. Their staff and hours of operation have been expanded. Also, online access to claims information should be available shortly. Please remember that Class 7 claims (those claimants with an implant made by Mentor, CUI, Baxter, Bioplasty or Bristol Myers) must be filed before May 31, 2006, but will not be paid until after June 1, 2007.

HORMONE REPLACEMENT THERAPY LITIGATION The first HRT trials will be held later this year. Unfortunately, we don't anticipate any trials in Florida or the federal system until 2006, primarily due to delays in obtaining critical documents from Wyeth. The plaintiffs have won a number of key rulings before Judge Wilson in Little Rock. **Alley & Ingram** is a member of the national steering committee for this litigation and is involved in reviewing the millions of pages of documents that have been produced. Depositions of key witnesses began in December and should continue through the summer. The documents that we have reviewed are shocking, and detail Wyeth's long-standing knowledge of the risks of breast cancer associated with Prempro and other combination hormone therapy, a refusal to fund any studies that might further assess the risks of HRT, and aggressive (and illegal) marketing for cardiovascular benefits and other indications for which the drugs were never approved or adequately studied.

FEN PHEN AND REDUX LITIGATION **Alley & Ingram** is currently preparing for trial in nearly 200 cases pending in Florida and the consolidated federal proceedings in Philadelphia. Many of our clients and their treating physicians are being scheduled for depositions. We anticipate participating in more than 700 depositions in these cases over the next 7 months. While concerns about Wyeth's financial viability remain, Wall Street analysts believe that the company can withstand this litigation, especially after court approval of some significant changes to the class action settlement. There have been a number of plaintiffs' verdicts over the past couple of months, but those verdicts have been relatively small compared to the significant costs in obtaining them. We are hopeful that the court will streamline the trial process in order to reduce costs and increase recoveries for plaintiffs. We are also hoping that the additional plaintiffs' verdicts as well as pressure from shareholders and Wall Street will force Wyeth to reassess the effectiveness of its current litigation tactics which have driven up the costs of the litigation dramatically and decreased the company's reserves to be used for verdicts and settlements.

VIOXX LITIGATION **Alley & Ingram** was one of only two firms with a Vioxx lawsuit pending in Florida prior to the drug's recall on September 30, 2004. We have been involved in the litigation for several years now. Currently, there is an effort to coordinate all of the newly-filed cases in federal court. Unfortunately, the progress of the cases filed prior to the recall has been stalled somewhat, but we anticipate that the litigation will regain its momentum shortly. On the positive side, now that the drug has been recalled, plaintiffs will be entitled to obtain a greater number of documents and information from Merck. Since the current status of Celebrex and Bextra is somewhat precarious, it is possible that this federal consolidation could be expanded in the future to include these additional drugs (especially if they are also pulled from the market).



Reforming the FDA



*T*he recall of Vioxx and resulting Congressional hearings has shed light on some long-standing internal problems at the Food & Drug Administration. David Graham, an FDA scientist, has spoken out about serious problems at the Agency that are threatening the safety of patients. These investigations have been fueled by the leak of a few internal Merck documents to the press. All of the other documents produced by Merck in lawsuits across the country are under seal, so the public and government officials have only received a small glimpse into Merck's knowledge of the dangers of Vioxx. Most people believe that the FDA is an independent governmental agency, far removed from political pressures, that has hundreds of scientists who are conducting safety testing on new drugs. In fact, the FDA does not conduct any of its own safety testing, and, instead, has placed the pharmaceutical companies on the "honor system" and require them to submit their own test results to the FDA for review. This system places too high of a burden on the FDA. In addition, we have seen a number of documents detailing efforts to influence the FDA's review of drug applications by members of Congress and other prominent governmental employees. The current Administration has strong ties to the pharmaceutical industry which has led to various efforts to limit the rights of those who have been injured. For example, the FDA's attorneys have partnered with law firms defending pharmaceutical lawsuits and are frequent speakers at defense lawyer conferences and have even filed briefs urging courts to dismiss lawsuits involving defective drugs. Also, the FDA has refused to allow any of their employees to be deposed and has delayed production of critical documents in various lawsuits. The Vioxx recall and resulting intense scrutiny of the FDA will hopefully help to reform the Agency and restore its legacy as the best drug safety organization in the World. The controversy has also led to reforms in the industry. Some drug companies are agreeing to publish all study data regarding their drugs, rather than just publishing those studies that are favorable. Great strides will be made if all drug companies agree to full disclosure. There is also a movement for the FDA to require drug companies to show not only that a new drug is safe and effective but that it is also an improvement over older drugs that are cheaper and have a longer track record of safety. Even if the FDA does not implement this requirement, many HMOs and managed care organizations are now requiring proof of effectiveness as a cost-cutting measure.

Drug & Medical Device Litigation

*W*e are currently litigating or investigating claims involving a number of drugs and medical devices. Please contact us if you have suffered injuries as a result of your use of any of these products:

- **Vioxx**
- **Bextra**
- **Celebrex**
- **Baycol**
- **Failed Medical Devices**
- **Permax**
- **Ephedra**
- **Prempro**
- **Hormone Replacement Therapy**
- **Dow Corning Breast Implants**