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Celebrex - Overview

Today, arthritis and its related conditions affect about one in every three Americans, and is the leading cause of disability in the United States, according to the Centers for Disease Control and Prevention (CDC). Rheumatoid arthritis, in which the immune system mistakenly attacks and damages healthy joint tissue, affects more than 2.1 million Americans, roughly three-fourths of who are women. In addition, osteoarthritis, in which the cartilage in the joints of the hands, hips, knees or spine deteriorates from normal use, affects most people over 60.

Celebrex, the brand name of the generic drug celecoxib, was approved by the U.S. Food and Drug Administration (FDA) on December 31, 1998, for the treatment of rheumatoid arthritis and osteoarthritis and, on December 23, 1999, as a drug treatment aimed at reducing the number of intestinal polyps in patients with a rare genetic disorder called familial adenomatous polyposis (FAP), an inherited disorder that, if left untreated, always develops into colon cancer. Celebrex is a non-steroidal anti-inflammatory drug (NSAID), and is in a class of drugs commonly referred to as "Cox-2 inhibitors."

Although steroids are considered safe for brief use to reduce inflammation, when taken for longer periods, they can cause serious side effects like weight gain, fluid retention often visible in the face, sudden mood swings, muscle weakness, blurry vision, increased body hair, osteoporosis (bone weakening), high blood pressure, stomach irritation, and/or glaucoma. Consequently, NSAIDs are preferred for the reduction of inflammation if steroids can be avoided.

Celebrex works by preventing the formation of "inflammatory" prostaglandins. These compounds are produced by the enzyme "cyclooxygenase 2," commonly referred to as "Cox-2," and are believed to cause pain and inflammation, as well as prevent blood cells from sticking together. Unlike other NSAIDs, Celebrex does not also block a second enzyme, commonly called "Cox-1," which monitors and maintains stomach tissue. Since this enzyme protects the stomach lining, Celebrex has been promoted as being able to reduce pain and inflammation without also causing ulcers and gastrointestinal bleeding.

Health Concerns Regarding Celebrex

Since its FDA approval, health concerns have been raised regarding the use of Celebrex. In April 1999, for instance, the *Wall Street Journal* reported that the manufacturer of Celebrex (Pharmacia, later acquired by Pfizer) had recently submitted adverse events reports (AER) to the FDA, linking 10 deaths and 11 cases of gastrointestinal (GI) bleeding to the use of Celebrex. This resulted in a rapid decrease in Celebrex sales.

However, further research led to another article that admitted several doctors who evaluated the AERs on Celebrex could find no evidence to suggest that the drug was solely responsible for the deaths. In fact, according to the FDA-approved label, among the population of people taking Celebrex, some deaths and ulcers were to be expected; a total of ten deaths was lower than anticipated, according to some doctors. One doctor cited in the article suggested that for 2 million people taking older NSAIDs for 3 months, 821 bleeding ulcers and 123 deaths would have been expected. In addition, more information about the histories of the victims was released. Of the ten deaths, it was reported that eight of the individuals had prior histories of heart, liver, or gastrointestinal problems.

These explanations resulted in restored faith in the safety of Celebrex, and sales began to climb again. But at about the same time, the FDA had started receiving reports regarding patients taking Celebrex with warfarin, a blood thinner used to reduce blood clots that is important in the prevention of heart attacks, strokes, and blockage of major veins and arteries.

The FDA had learned of cases in which patients taking Celebrex and the drug Coumadin (generic name warfarin) concurrently experienced "bleeding events," and thus required Pharmacia to include warnings in its promotional materials of this risk, and advise healthcare professionals and patients to monitor anitcoagulant activity in patients taking the two medications concomitantly.

In May 1999, the FDA announced a labeling change relative to Celebrex. The labeling change instituted by Pharmacia reported that patients on warfarin were at an increased risk of "bleeding complications," such that caution should be used in prescribing Celebrex to them. This labeling change was not satisfactory to the FDA, however, and on February 1, 2002,

the FDA sent Pharmacia a "Warning Letter," requiring the manufacturer to cease certain promotional activities that minimized the risk of excessive bleeding when Celebrex was taken concomitantly with warfarin.

Additionally, an article published in the August 2001 *Journal of the American Medical Association* (JAMA) raised concerns over Celebrex's possible impact on cardiovascular health, implicating Celebrex in heart attacks and other heart irregularities. Although doctors rushed to write rebuttal letters, in September 2001, the American Heart Association, the National Stroke Association and the Arthritis Foundation asked Pharmacia to test whether Celebrex increased the risk of heart attacks and strokes. Pharmacia disputed the findings reported in JAMA and insisted Celebrex is safe. Although the researchers for the JAMA article analyzed four studies that were not designed to examine the drug's effects on the heart, until further research is done, patients with heart disease should question their doctor regarding the safety of Celebrex.

Recent Developments: NIH Halts Use of Celebrex in Large Cancer Prevention Trial

On December 17th, 2004 the National Institutes of Health (NIH) announced that it has suspended the use of COX-2 inhibitor celecoxib (Celebrex) for all participants in a large colorectal cancer prevention clinical trial conducted by the National Cancer Institute (NCI). The study, called the Adenoma Prevention with Celecoxib (APC) trial, was stopped because analysis by an independent Data Safety and Monitoring Board (DSMB) showed a 2.5-fold increased risk of major fatal and non-fatal cardiovascular events for participants taking the drug compared to those on a placebo.

In the APC clinical trial, patients taking 400 mg. of Celebrex twice daily had a 3.4 times greater risk of cardiovascular events compared to placebo. For patients in the trial taking 200 mg. of Celebrex twice daily, the risk was 2.5 times greater. The average duration of treatment in the trial was 33 months. However, a similar ongoing study comparing Celebrex 400 mg. once a day versus placebo, in patients followed for a similar period of time, has not shown increased risk.

Both the manufacturer of Celebrex (Pfizer) and the FDA are currently evaluating the data from these studies.

Also on December 17, the FDA asked Pfizer to voluntarily suspend direct-to-consumer advertising on Celebrex during the time the FDA is obtaining and evaluating the new and conflicting scientific data on adverse events associated with the drug. FDA also requested Pfizer change the information provided to physicians to reflect the recommendations FDA made encouraging physicians to consider alternative therapies as they evaluate their individual patient needs. Pfizer agreed to suspend its Celebrex promotion and to craft appropriate detailing to physicians that reflects the uncertainty of scientific data currently available.

Common Side Effects of Celebrex

In addition to the serious side effects listed below, some common, but less serious side effects associated with Celebrex include:

- Headache
- Indigestion
- Upper respiratory tract infection (a "cold")
- Diarrhea
- Sinus inflammation
- Stomach pain
- Nausea

Who Should Not Take Celebrex

According to Pfizer, patients should not take Celebrex if they have aspirin-sensitive asthma, or allergic reactions to aspirin or other arthritis medicines or certain sulfa drugs called sulfonamides, or if they are in their third trimester of pregnancy.

Special Warnings with Celebrex

Celebrex and other NSAID medicines can cause stomach ulcers that bleed. The chance of this serious problem increases the longer you take Celebrex and with higher doses of Celebrex. Stomach bleeding can also happen suddenly while you take Celebrex. Stop taking Celebrex and call your healthcare provider right away if you get:

- A burning stomach pain;
- Black bowel movements that look like tar;
- Vomit that looks like blood or coffee grounds.

Celebrex and other NSAID medicines can cause serious allergic reactions that include swelling of the face, lips, tongue or throat. These allergic reactions may cause problems with breathing, swallowing, and wheezing. Serious allergic skin reactions have also been reported with the use of NSAIDs. If you experience any of these symptoms, contact a physician immediately.

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