

FDA panel to weigh second chance for new class of painkillers

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Trials halted in 2010 after some taking the drugs may have overworked damaged knees, needed surgery.

(HealthDay) -- A U.S. Food and Drug Administration advisory panel on Monday will weigh the wisdom of allowing new clinical trials of a class of powerful painkillers for osteoarthritis. The drugs may have worked so well for some patients that those patients wound up needing knee replacement surgery because they overworked their already damaged joints.

Studies of these painkillers were halted in 2010 because of this troubling side effect, and at the time Dr. Nancy Lane, lead researcher on a trial looking at one of these drugs, tanezumab, said patients who ended up needing a knee replacement most likely harmed their damaged joint even further because they felt so good.

"They probably accelerated the degeneration of the joint," said Lane, director of the Aging Center, Medicine and Rheumatology, at the

University of California, Davis. "Sometimes, [pain](#) is good in protecting you."

However, there was some evidence that when these drugs were given with another common [painkiller](#), a reaction occurred that might have caused the problem.

In addition to tanezumab, which is made by [Pfizer Inc.](#), trials of two similar drugs were also stopped. These drugs were REGN475, made by Regeneron Pharmaceuticals, and fulranumab, made by Johnson & Johnson.

Now, the three companies are expected to argue that these drugs, known as anti-nerve growth factors (anti-NGFs), are needed by many patients suffering from [osteoarthritis](#). They are proposing to run trials using the drugs at lower doses and without other pain medications such as Advil. In addition, they are expected to tell the expert panel they will be more selective in which patients they recruit for their research.

One of the questions the panel is being asked to consider is whether, given the risk of these drugs, are there any groups of people who would benefit from them?

Dr. Elaine Tozman, an associate professor in the division of [rheumatology](#) and immunology at the University of Miami Miller School of Medicine, said she doesn't think this new painkiller would add much to the treatment of osteoarthritis.

"This is really a drug which is for a symptom of osteoarthritis, it's really for pain," she said. "As rheumatologists, most of us are looking for a drug that works on the underlying disease."

Tozman noted that patients with severe osteoarthritis of the knee usually

go on to have a joint replacement.

However, the companies will try to convince that panel that there are millions of people who could benefit from these drugs.

"Based on the assessments of risk and benefit, we conclude that further clinical investigation of tanezumab in osteoarthritis and other forms of [chronic pain](#) is warranted with the protection of additional risk management and surveillance measures," Pfizer said in FDA briefing documents. "Chronic pain affects millions of adults in the United States. For many patients, treatment of chronic pain is inadequate in part due to the limitations in the availability of effective treatments and inadequate patient and clinician knowledge about the best ways to manage chronic pain."

For its part, Regeneron stated "... there may be a role for anti-NGF therapy in pain conditions where there is a high unmet need, i.e., those for which there are no adequate alternatives."

Although the FDA is not required to follow the recommendations of its advisory panels, it usually does.

Lane said tanezumab, which is given by injection, should probably not be used frequently. The effect of the drug can last at least eight weeks, she added, but no studies have been done yet on its long-term effects.

The [drug](#) works in a unique way by blocking nerve growth factor (NGF), which is essential for normal development of the nervous system but is also released when there is inflammation. NGF stimulates nerve cells and triggers pain, Lane explained.

"By inhibiting NGF, we really get a dramatic reduction in pain in patients who have pretty severe osteoarthritis," she said. "It doesn't do

anything to the disease, it doesn't hurt your stomach, it doesn't change how you think or make you groggy. This is a real game-changer."

In addition to osteoarthritis, tanezumab was also being testing in patients with cancer pain, interstitial cystitis, chronic low back pain and diabetic nerve pain.

Some 27 million adults in the United States have osteoarthritis, with the knee being the most affected joint, according to the U.S. Centers for Disease Control and Prevention.

The number of people with osteoarthritis of the knee is expected to rise as baby boomers age and as obesity among Americans increases, Lane noted.

More information: For more on osteoarthritis, visit the [U.S. National Library of Medicine](#).

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