

CURE ARTHRITIS NOW!

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Division of Dockets Management
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Joint Meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee

To Whom It May Concern:

Cure Arthritis Now! supports efforts to determine the safety of and risks associated with COX-2 inhibitors. We urge you, however, *not* to remove this important class of drugs from the market. COX-2 inhibitors may not be the best treatment for all patients but, when prescribed appropriately, these medications *are* the best treatment for some arthritis patients.

ARTHRITIS IS A COMMON, PAINFUL AND DISABLING DISEASE.

There are an estimated 70 million adults in the United States today with arthritis or chronic joint symptoms. Arthritis is the leading cause of disability in the Nation, costing our country an estimated 86 billion dollars annually--\$31.5 billion of that is from indirect costs such as lost productivity. In addition, arthritis in its more than 100 different forms, causes a great deal of chronic pain and suffering. Arthritis patients need access to a wide range of medications to retain or regain their quality of life.

NSAIDS AND COX-2 INHIBITORS ARE NECESSARY FOR MANY ARTHRITIS PATIENTS.

Because there is no cure for arthritis, anti-inflammatory medications are an *essential* part of the treatment plan for the majority of arthritis patients. Often one of the *only* treatments available for a patient (e.g. many osteoarthritis patients) is anti-inflammatory pain relievers such as NSAIDS and COX-2 inhibitors. And even for those arthritis patients who have other treatments available to them, anti-inflammatories are often prescribed in conjunction with the patient's other medications. NSAIDS and COX-2 inhibitors play a vital role in limiting the pain and disability of arthritis.

ARTHRITIS PATIENTS NEED ACCESS TO A BROAD RANGE OF TREATMENTS.

The treatment that works for one patient will not necessarily work for another patient. Because the arthritis population tends to be older, and because arthritis is so common, arthritis patients frequently suffer from co-morbidities. It is imperative that arthritis patients have access to a broad range of treatment options because a medication appropriate for one patient may not be the best choice for another patient. For example, a patient at high risk of GI side effects would not be prescribed ibuprofen, and it may be that a patient at high risk of cardiac side effects would not be prescribed COX-2 inhibitors. Patients who cannot take traditional NSAIDS *need* another choice. The solution is to educate patients and physicians about the risks and contraindications of drugs, not to simply remove drugs from the market. If the risks and contraindications of COX-2 inhibitors

are known to patients and physicians, those drugs will be prescribed only when they are the best choice for a patient.

ALL ARTHRITIS TREATMENTS HAVE SOME RISKS, SIDE EFFECTS OR CONTRAINDICATIONS.

No medication comes without some risk. For example, traditional NSAIDS are associated with increased risk of GI bleeding and cause an estimated 16,500 deaths each year.¹ In addition, Methotrexate, Enbrel and Remicade, often prescribed for Rheumatoid Arthritis, have risks of severe side effects and require periodic blood tests and monitoring by a physician. Arthritis patients given full informed consent are willing to accept these risks in an effort to minimize the pain, decreased mobility and other effects of their disease. For arthritis patients who live with daily pain, the benefits of these medications outweigh the risks.

Once again, we urge you not to remove this important class of medications from the market. Prescribed appropriately, COX-2 inhibitors are an important piece of the arthritis treatment puzzle. Although this class of drugs may not be appropriate for every patient, they are appropriate for some patients. Please don't remove a valuable treatment choice from patients who may not have a lot of choices available to them.

Thank you.

Sincerely,

Karen A. Vicari, JD
Executive Director

¹ Singh G. et al. J Rheumatol. 1999 26 (suppl 26): 18-24