



*Research...Access to Treatments...Cure*

**Statement by Michael Paranzino, president, *Psoriasis Cure Now!*,  
to the Joint Meeting of the FDA's Arthritis Advisory Committee  
and the Drug Safety and Risk Management Advisory Committee,  
regarding COX-2 NSAIDs**

February 3, 2005

*Psoriasis Cure Now!*, a nonprofit patient advocacy group, appreciates this opportunity to address this Joint Meeting on behalf of the more than one million Americans with psoriatic arthritis.

Psoriatic arthritis is an incurable disease that causes inflammation in and around the joints, and usually also involves the skin symptoms of psoriasis. While mild for many, its symptoms can also be disabling; and as a progressive disease, it often becomes more problematic over time. Morning stiffness, joint pain and fatigue are also common for those with psoriatic arthritis. The joints in some cases become disfigured.

Psoriatic arthritis is a disease that receives little attention. For example, while funding for the National Institutes of Health (NIH) has soared 148% over the last decade, psoriasis-related research at NIH's National Institute of Arthritis and Musculoskeletal and Skin Diseases was actually *down* 13% during that same time. Research on psoriasis and psoriatic arthritis receives just 77 cents per patient annually, despite the untold pain and suffering it causes and its cost to the U.S. economy of billions of dollars annually.

(Psoriatic arthritis also receives scant media attention, although it did figure prominently in last year's movie "The Singing Detective" with Robert Downey Jr. But public awareness is low.)

With that background, we would like to make five points that we hope the Committees and the FDA will consider as they continue to work on these issues.

First, psoriatic arthritis is a serious disease, and it can have a devastating impact on a patient's quality of life. Many patients with psoriatic arthritis depend on the very drugs that are the subject of this hearing. Without them, their pain will increase and their productivity and quality of life will plummet. While considerable media attention has focused on alleged overuse of these drugs by relatively healthy individuals, the fact is that many patients are taking these medications for one reason: because they have to. Naturally, many are feeling

confused, frustrated, and afraid due to the troubling news we keep hearing about the safety of various COX-2 inhibitors.

(I must add here as an aside that at a Joint Meeting of the FDA's Dermatologic & Ophthalmic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee last July, a few members of the Committees displayed a disappointing attitude that suggested they did not fully grasp the seriousness of psoriasis for many Americans. We trust that was an aberration, as psoriasis and psoriatic arthritis are often extremely debilitating diseases.)

Second, drugs that relieve arthritic pain and inflammation should not lightly be denied to patients, even if they carry significant risks. In most cases, the risks should be conveyed as thoroughly as possible to the patient, while leaving it to the patient, working with his or her physician, to decide whether in his or her particular case, the benefits of taking a drug will exceed the risks. An Advisory Panel, or government regulator, is seldom going to be in the best position to determine for every American that the risks of a drug exceed the benefits a particular patient may receive from the medication. So we urge great caution and restraint before drug bans are imposed.

Third, everyone—regulators, industry, the medical community, the media, patient advocacy groups—must do a better job of communicating to the public what we know and what we do not know about the risks of these drugs. A statement, for example, declaring that a drug doubles the risk of heart attack, without providing context, is more confusing than educational for the typical patient. Did it double the risk from a 1 in 100 annual chance to a 1 in 50 chance? That would rightly alarm most people. Did it double the risk from a 1 in 2 million annual chance to a 1 in 1 million chance? If it improves your quality of life, you might sensibly accept that risk. Countless news reports in recent weeks have included discussions of heightened risk that are devoid of essential context. This is a disservice to patients.

Fourth, we should acknowledge that clinical trials are conducted with a relatively small number of people. This underscores the importance of continuing to study a drug after it receives FDA approval. While we need to get new drugs to market quickly, as patients are in dire need now for better treatments for a whole host of diseases, post-marketing surveillance must be improved.

Finally, the challenges we face with these drugs emphasize the need for additional biomedical research funding for the National Institutes of Health. Many people whose pain had subsided are in pain again. They need additional options. Aggressive NIH funding, and a robust biotech/pharmaceutical industry, are essential to bringing relief to patients at the earliest possible time.

Thank you for holding this important hearing and for considering the needs of psoriatic arthritis patients as you make your recommendations to the FDA.

*Psoriasis Cure Now!* encourages you to contact us if we can ever be of service.

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