

**FACSIMILE COVER PAGE**

**MESSAGE:**

Dear Ms. Topper:

Please accept this FAX as my statement of position regarding the subject open public hearing under docket number 01N-0256.

Thank you.

Sincerely,

James P. Royce  
2182 East Avenue  
Hayward, CA 94541



To: Kimberly Topper	From: James P. Royce
Fax #: 1-301-827-6801	Fax #: 510-538-1600
Company: Food and Drug Administration, CDER	Tel #: 510-538-8630
Subject: docket number 01N-0256	
Sent: 8/17/2001 at 4:52:52 PM	Pages: 16 (including cover)

## James P. Royce

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August 17, 2001

[topperk@cder.fda.gov](mailto:topperk@cder.fda.gov)

Kimberly Topper  
Food and Drug Administration, CDER  
Advisors and Consultants Staff, HFD-21  
5600 Fishers Lane,  
Rockville, Maryland 20857

Your Reference: Docket Number 01N-0256

Dear Ms. Topper:

By way of background, I was originally injured on May 17, 1973. This was a catastrophic spinal cord injury involving levels from T6 to S1, and initially I required surgeries and fusions from L1 to S1. The nature of the injury is that it causes severe pain. Bony spurs, fragments, and dislocated vertebrae are continually interfering with the spinal roots. I experience chronic recurrent intractable pain in nearly all areas below the waist.

During the days and years following my initial injury in 1973 chronic pain sufferers such as myself were treated by the medical profession as if we were drug seeking addicts whose main goal in life was to obtain opiate narcotics. It was explained to me by various medical professionals at "Pain Clinics" that any pain that lasted more than a few months was considered to be Chronic Pain and that it was not really "legitimate" pain. Therefore, because of these attitudes by the medical profession, we were not treated like patients who needed pain medication.

The laws were written in such a way that if any one physician, even one as famous and accomplished as Dr. James Morris, who was a full professor of orthopedic surgery at University of California San Francisco Medical Center, were to prescribe narcotics for pain, he would risk immediate disbarment from the California State Board of Medical Quality Assurance and/or the FDA. On several occasions he apologetically advised me of this, explaining that this was the reason he had to stop giving me prescriptions.

I remember sitting in Dr. Morris's waiting room at University of California in San Francisco and talking with other patients such as myself. To a person, all of us were seeking pain relief.

This was truly a tragic situation.

This is in stark contrast to the way patients are treated today. Now, when I enter my physician's office, I am asked if I am in pain. There is a separate specialty called "Pain treatment specialist." There are doctors such as Dr. Elliot Krames and Dr. Marilee Schuchard who are pain treatment specialists and whose education and background enable them to adequately prescribe pain medication that is both appropriate and necessary for the treatment of pain.

I am in a unique position to have been initially injured during the early 1970's and to have experienced the way it was then, in stark contrast to the way it is now.

In the 1970's I suffered daily. My main thought of the day was how I was going to obtain enough pain medication to survive.

Now, I am more concerned with other more constructive interests, such as my volunteer with the Sierra Club San Francisco Bay Chapter, and with helping other patients who suffer from chronic pain.

I appeal to the members of the FDA to please not return me to the days of the 1970s when the War on Drugs was fought on the backs of patients who suffered from catastrophic back injuries. It will always be true that there are people who abuse pain medication. This will be true no matter how laws are written.

I appeal to you to please not return us to the days when the war on drugs was fought on our backs.

In January of 2001, the Joint Commission on Accreditation of Healthcare Organizations issued new humane pain treatment standards. These require hospitals, healthcare facilities, nursing homes, and the like to treat patients' pain and to inform patients that they have a right to effective treatment of their pain.

This is in stark contrast to the days of the early 1970's when patients such as myself were routinely ignored and mistreated.

The recent shift in media coverage regarding pain, the emphasis on deaths caused by OxyContin, the appearance in national publications like the New York Times, Newsweek, and the U.S. News & World Report have portrayed opiate pain medications as if they are responsible for deaths and suffering instead of required as a tool for the treatment of chronic pain.

Kindly read Sandeep Kaushik's "*Oxycon Job-The Media-Made OxyContin Drug Scare*" at <http://www.freetimes.com/issues/933/features-coverstory.php3>. A copy of that article is attached for your reference and information. This article is typical of the scare tactics that are wreaking havoc in the chronic pain community. Patients who suffer from chronic pain are again being forced to defend their legitimate need for medication.

Patients such as myself and countless others need for you to listen to our pleas. We are suffering right now from chronic pain. We do not want to spend the rest of our lives struggling with the FDA or our local Medical Boards over pain control issues. We want to spend our time with our families and pursuing life goals.

I strongly urge the FDA to stand with people such as myself who suffer from chronic pain. Please consider the needs of those of us who are suffering from catastrophic spinal cord injuries, from diseases that cause severe chronic pain such as CRPS (Chronic Regional Pain Syndrome), and cancer.

We do not need, nor do we want the war on drugs to be fought on our backs.

Thank you for your consideration.

Sincerely,

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