

May 30, 2001

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1102 Parkside Drive  
Ormond Beach, FL 32174

Kimberly Topper  
Center for Drug Evaluation & Research (HFD-21)  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Dear Kimberly Topper:

I am writing this letter to express my opinions concerning the FDA Advisory Committee holding hearings to discuss the medical use of opiate analgesics in various patient populations, including pediatric patients and patients with chronic pain of nonmalignant etiology, as well as the risk to benefit ratio of extending opiate treatment into these populations. I understand these hearings will also address concerns regarding the abuse potential, diversion and increasing incidence of addiction to opiate analgesics, especially to the modified release opiate analgesics. I think these hearings may be due to the recent spurt of media publicity about abuse of Oxycontin.

I am an oncology certified nurse working at a community hospital in Daytona Beach, FL. I am a teacher of oncology nurses and I have over 11 years experience in oncology nursing as well as over 31 years nursing experience. I have seen the terrible pain and suffering of cancer and I have also seen the "miraculous" pain relief and the return of dignity and quality of life at the end of life for those suffering patients by us simply "managing" their pain with around the clock pain medications such as oxycontin. It would be a real shame to lose a very useful drug due to this media blitz, or even due to misuse by those who are searching for things to abuse.

I would like to refer you to the AHCPR guidelines *AHCPR Publication No. 94-0592: March 1994* and other research and literature supporting the use of around the clock opiates for cancer pain. The WHO analgesic ladder is a simple, well-validated, and effective method for assuring the rational titration of therapy for cancer pain and has been devised by WHO (World Health Organization, 1990) and has been shown to be effective in relieving pain for approximately 90 percent of patients with cancer (Venta fridda, Caracein, and Gamba, 1990) and over 75 percent of cancer patients who are terminally ill (Grond, Zech, Schug, et al, 1991)

The five essential concepts in the WHO approach to drug therapy of cancer pain are:

- By the mouth.
- By the clock.
- By the ladder.
- For the individual
- With attention to detail

I also urge you to consider the underserved needs of the special populations of pediatrics, chronic non-malignant pain sufferers such as sickle cell, severe arthritis, unrelieved chronic back syndromes, and the elderly. **The elderly should be considered an at-risk group for the undertreatment of cancer pain because of inappropriate beliefs about their pain sensitivity, pain tolerance, and ability to use opioids. Elderly patients, like other adults, require aggressive pain assessment and management (Ferrel, 1991)** Pain management must be individualized and left up to the expert assessment of the healthcare providers.

I urge you and your colleagues to see the overwhelming positive evidence for continuing the healthcare provider's accessibility for prescribing of modified release opiate analgesics. All of our patients have The RIGHT to Pain Management.

Sincerely,

Ann M. Smith, RN, BS, OCN

