

May 25, 2001

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

Dear Ms Topper:

I would like to express my view regarding the upcoming discussion on the medical use of opiate analgesics in patients with chronic pain of nonmalignant origin. As a cancer nurse specialist, I have focused a great deal of my professional effort on pain management. In recent years I have broadened my work to include acute and chronic pain, as well as cancer pain. It seems that whenever we begin to make headway, to provide better pain management to our patients, the media creates an uproar, feeding the public phobia about opiate drugs.

Chronic pain remains a major problem, the major cause of disability in our country. The use of long-acting opiates for specific chronic pain patients, when their pain physician believes this to be the best plan of treatment, can increase function and get these patients back into life, often even back to work. I would refer you to the American Academy of Pain Medicine and the American Pain Society Joint Position Paper on the Use of Opioids for the Treatment of Chronic Pain, published in 1997. Long-acting opiates maintain a steady level in the blood, preventing peaks and valleys, so that not only is pain better managed, but the potential for sedation and other side effects is diminished. There is a very low addiction potential with long-acting opiates, when used as prescribed for pain control.

There is widespread misunderstanding of the nature, and even the meaning, of addiction. If, after a time on opiate drugs, a patient no longer has pain, he would experience physical dependence. This is not addiction; the medication can be successfully tapered off in a short time. Addiction, on the other hand, is a psychological dependence characterized by an obsession with obtaining and using a drug, or other agent, for a reason other than pain management, even in the face of personal harm.

While the patient receiving opiates for pain management improves function, in contrast, the addict loses functional status. Addicts will use anything, regardless of personal harm, to get a "high". It would be impossible to remove every item with potential for use by addicts from the market. Consider the following: White-Out, glue, various aerosols, cigarettes, and numerous plants are among those I know of having been abused, not to even mention a wide variety of illegal drugs. And, yes, these same people have figured out a way to abuse some of the long-acting opiate drugs, by overcoming the delivery system. And, most certainly, media hype about the "problem" has created the "problem". Addicts who hadn't thought of this most certainly know about it now! While I believe the pharmaceutical companies are working on delivery systems which will be more difficult to overcome, it would be a real shame to lose ground in chronic pain management due to some addicts' ingenuity and the media hype.

I would urge the committee not to further public fears of addiction and the appropriate use of opiate drugs. I would urge the committee not to add regulatory barriers to the effective use of opiate drugs.

Our patients in pain need the medications which effectively relieve pain. Long-acting dosage forms are the most effective way to treat both cancer pain and chronic pain.

Sincerely,



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