

ORTHOPAEDIC RECONSTRUCTION, P.C.

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

Dear Ms. Topper:

This letter supports the use of sustained release opiate analgesics, such as Oxycontin and others, for the use of nonmalignant pain.

As a true example, I would like to briefly recite the case of a 36 year old gentleman who had a motor vehicle accident in which his vehicle tumbled down an embankment and was not found for a twelve hour period. In this accident, he suffered a dislocation of the hip with a severe contusion to the sciatic nerve. After reconstruction of the hip, the sciatic nerve remained a source of severe pain. Now, more than two years post-injury, he remains functional on a sustained release opiate analgesic, but at no time has he been able to function either socially or at the work place without this medication. His need for the medication has not increased or decreased over the last year, and there is no sign of loss of effectiveness due to toleration.

There are many other such cases in my own practice and, I am sure, throughout the country. These individuals do far better on a sustained release smooth dosing system rather than the ups and downs that come with multiple doses of immediate release products given throughout the day. For a sincere user of these products, the tendency of the medication to "get away from them" is a lot less, with abuse potential actually less for sustained release products than for the immediate release products.

I hope that the Food and Drug Administration will not overreact to the abuse of sustained release products by withholding them from availability to appropriate patients.

Thank you for your attention.

Sincerely,



Daniel L. Zimet, M.D.

DLZ/brt