

August 15, 2001

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

Dear Ms. Topper,

My name is Katherine L. DeCarlo and I am writing regarding an upcoming meeting to be held by the FDA on September 13 - 14 2001 which will review the use of opiate controlled substances. I am a 33 year old woman who has been taking one of these opiate controlled substances, Oxycontin, for a few years now due to four spinal surgeries. One surgery fused my spine with the aid of two metal rods and six metal screws, my last surgery left me with a permanent carbon fibre disc at the lowest level of my spine, L5-S1. Before using the Oxycontin my doctors prescribed physical therapy, which I did and complied with but did not help alleviate my pain. I used a tens unit along with the therapy and other medications but still did not receive adequate pain relief.

For several years I used Lortab, Lorcet or Vicodin which, as you know, contain high percentages of Tylenol which damages the liver with continual use as I was receiving. Finally my current physican prescribed Oxycontin. This very controversial drug has helped me regain some of my life by aiding me with pain control. I am able to do things that were unthinkable prior to the drug. Now, I am able to walk through a shopping mall without having to have my husband take me home so I could lie down. I am able to sit with family and eat a meal, having to stand only once or twice. My life has improved a great deal with the addition of this drug.

Whenever I read a magazine article or watch the nightly news and see how this drug has become a much sought after illegally used substance, I cringe. This medication has helped me so much it sickens me to think about the weak willed people that use it illegally to get 'high'. This drug, which is legally prescribed to me, does not get me 'high'. It just kills my pain.

I wonder when this society is going to make the person who does the wrong be held responsible instead of punishing the person who needs the medication. By making this medication harder for my physican to prescribe, I am the person who will be punished, I am the person who will face the daily unrelenting suffering of chronic pain.

I am writing so that my voice as a voter who has suffered the consequences of unrelieved pain will be heard and counted. I hope I have succeeded in both.

Sincerely,

Katherine DeCarlo

To be posted under docket number 01N-0256