

Mel Stein
75 N. Grove Street
Rutland, VT 05701
July 17, 2001

Kimberly Topper
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Ms. Topper:

I am writing in response to published reports concerning the drug Oxycontin. As I understand these reports, there are to be hearings in Washington to possibly regulate this particular medication more than it is already. This bothers me greatly.

First of all, the fact that legislators are responding to a "crisis" declared by the media concerns me. Based on the total number of abusers of this medication, the time could be better spent elsewhere. Tobacco is responsible for a far greater number of deaths and time lost from work without having any positive aspects.

Secondly, this medication is already as tightly regulated as possible, while still being available to the medically needy patient. Therefore, further regulation is not practical.

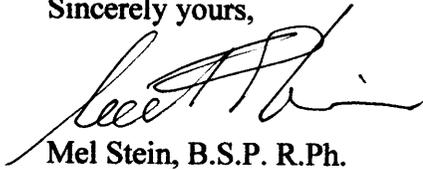
Thirdly, and lastly, AND MOST IMPORTANTLY, this is a very valuable medication. I happen to be able to view this from two different perspectives. As a Registered Pharmacist, I see prescriptions for Oxycontin on a daily basis. With very few exceptions, the patients who have prescriptions for this medication are able to go on with their lives thanks to the pain relief they receive from Oxycontin. Most suffer negligible side effects and some would be incapacitated were it not for Oxycontin. One of the features of this medication is its dosage schedule. It is given every 12 hours. This allows for a steady stream of medication in the body and lessens the fluctuating blood levels of an "as needed dosage" medication. By staying ahead of the pain the patient can go about his/her daily tasks relatively pain free. As a pharmacist I know that without Oxycontin the use of "every 4 hours as needed" drugs would greatly increase. Along with this increase would come a plethora of unwanted side effects; as well would come a "crisis of abuse" from the media about these medications. Unfortunately, these types of medications would tend to be overused as the patient would always be behind the pain and trying to get ahead.

My other perspective on Oxycontin is as a patient. I have suffered from numerous knee injuries as well as osteoarthritis for many years. I have had six or eight surgeries including an osteotomy and bilateral knee implants. The latter one is the real source of

my trouble. For the last 2 years, since the last knee implant, I have suffered from chronic pain at the sites of the implants as well as the site where the implant impacts the osteotomy site. Along with my orthopedic surgeon and pain specialists we have been able to control the pain by using a combination of micro-electronic stimulation, medications and physical activity. Oxycontin is one of the medications which I take as part of this multi-faceted approach. There is no doubt in my mind, that without Oxycontin my daily life would be very different. The use of this medication allows me to go to work full time as a retail pharmacist. I spend 12 hours a day on my feet in the prescription department of a community pharmacy. I do this 40 hours a week, and sometimes as many as 60 hours. I suffer no ill side effects, no drowsiness, no upset stomach, no lightheadedness, all of which I have experienced while using "as needed" medications. As I write this my physician and I are trying other medications in an attempt to reduce or eliminate my use of Oxycontin. Not because it is dangerous, but because we are trying to eliminate my pain. Until we are able to do this, however, I hope to be able to have Oxycontin as one of the weapons against pain in my arsenal.

I hope nothing is done that would change the availability of this medication. Its use, as part of the total picture allows me to have a "normal" daily life, with my wife, children and grandchildren, while I pursue a time when I will be pain free.

Sincerely yours,

A handwritten signature in cursive script, appearing to read 'Mel Stein', written in black ink.

Mel Stein, B.S.P. R.Ph.