



CHERRY WAY ORTHOPAEDICS, P.C.

Mark R. Foster, Ph.D., M.D., F.A.C.S.

September 14, 2001

Kimberly Topper
Food & Drug Administration, CDER
Advisors and Consulted Staff
5600 Fishers Lane, HFD-21, 50-100
Rockville, MD 20857

Dear Ms. Topper:

I have been a frequent prescriber of OxyContin, as my orthopaedic surgical practice involves a focus on spine surgery and spinal conditions, and consequently I have a lot of patients with chronic pain.

On behalf of many of those patients who have expressed terror and fear at the possibility that they would no longer be able to get the OxyContin, which has positively changed their lives, I write this letter.

There have been problems with OxyContin and I am aware of those and have actually (unfortunately) had to deal with those problems. First, I understand that pharmacists have had theft. My response to that is that we have not eliminated money because Willy Sutton robbed banks. OxyContin is worth \$1.00 per milligram on the street and might as well be cash. When you have something that is valuable, desired and marketable, adequate security is a necessity.

There are problems with abuse of OxyContin. Effectiveness is not a bad thing for those people who need relief of their pain to resume function, and have resumed having a real life, as they might have once known it. The fact that some people break the pills for immediate relief is really and truly a problem; however the patient's who benefit from this medication plead with you not to restrict it in any way because of abusers. Further, it will remain incumbent upon the company to do whatever they can to produce a formulation that still is released for availability, reliably and predictably for the patient treatment, which is resistant to these matters of abuse, but it is never possibility to idiot-proof anything because idiots are too inventive.

This week, I received a notice from a health plan regarding a prescription that I never wrote about a patient that I had never seen. I was doctor number seven and these were all narcotics. We all know that people come in and say that they took one of their uncle's Percocet, and could I please prescribe those, as they worked very well.

People carry extra batteries for flashlights. They try to have money in the bank for a rainy day and people like to have painkillers on the shelf "in case".

I tell people I do not treat possibilities, I require an examination and treat present problems or actualities. Nonetheless, some people even like to have some spare antibiotics around in case they get a sore throat, just to make sure that they do not get strep. That is not medically appropriate but it happens. Purdue intends to provide prescriptions that cannot be photocopied and I have been subpoenaed to testify that the prescriptions being presented to pharmacies were not authored by me. In fact they were by family members of a former patient who had abused the drug and continued to generate fraudulent prescriptions. This is a crime and this is something that goes into the criminal justice system, this is not a matter of regulation. People die in car accidents but cars are appropriate for transportation (albeit arguably there is a blind spot for public transportation, but that is beside our present discussion). OxyContin has an enormously valuable role for many of my patients who are already in fear and terror

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that restrictions might prevent them from having the present pain relief and resumption of function, many even in fact work and have careers, without the medication.

There are alternatives, but I have heard of a mortician who took two Fentanyl patches off of a corpse, went out of the office, and was found dead from an overdose of Fentanyl. There are many stories of inappropriate disposal and in fact most major hospitals fail to have a disposal policy, which should be absolutely mandatory. MS-Contin was far less tolerated from a gastrointestinal standpoint and is made by the same company. Short-term medications prevent people from living their lives without absolute dependence upon the pill that they have to take on a frequent basis. Any knowledgeable person or experienced pain manager will uniformly present to you with the World Health Organization and the American Pain Society have presented for many years; long term medication should be slow release, as is OxyContin. This is what we have needed for chronic pain patients and now we are at risk of putting these patients back in the prison of "is it time for my next pill?" because of the quality of the relief of pain that occurs.

Studies have shown that people in favor of euthanasia, or right to die, have had a reversal in some studies of over 90% of those opinions when they were assured of adequate pain relief. I would suggest that the right to die movement is testimony to the under treatment of pain, the fear and intimidation of physicians by regulatory agencies, particularly the DEA and probably sincere prosecutors, who are out of line to force people to go without the medication that would be appropriate and which is otherwise available. People are scared that they will die in uncontrollable and unbearable pain. We have medication. We have hospice organizations growing around the country and patients who are aware of hospice, who have known people who were dying and in pain from cancer or other problems, have almost uniformly reversed (in terms of polls) their opinions with regard to being put out of their misery.

Any regulation prohibiting OxyContin would be in my mind contributory to the public fear, for actual good reason unfortunately, that pain is ignored, overlooked and under treated and the Government wants it that way. The Government has no business having an opinion about whether or not people can have the pain relief that they should. Regulation and law enforcement may have a problem but the competitors to Purdue and OxyContin should not be allowed to profit with inferior medications and legitimate access to this medication should not be deprived, if patients would be able to live a more normal life with it.

Thank you for your kind consideration.

Sincerely,



Mark R. Foster, Ph.D., M.D., F.A.C.S.

MRF/sab

cc: Richard Correra

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