

CHARLES S. EYTEL, M.D.

400 EIGHTH STREET NORTH
NAPLES, FLORIDA 34102

(941) 649-3311

DIPLOMATE OF AMERICAN BOARD OF INTERNAL MEDICINE
SUBSPECIALTY: HEMATOLOGY/ONCOLOGY

August 8, 2001

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

RE: Docket No. 01N-0256

Dear Ms. Topper:

As a practicing medical oncologist and internist I have some major concerns over your agency's potential response after the upcoming hearing your agency is having in response to the recent media hype over the disturbing events from the illegal channeling and recreational use of the product OxyContin®. Having graduated medical school in 1962 and completing my Fellowship in 1968 I have had vast experience in prescribing for patients suffering from chronic pain of both a malignant and nonmalignant nature. I have utilized all of the modified release opiate analgesics commercially available since their FDA approval. My experience with these agents has been most gratifying. The ability to titrate the patient's requirements for analgesia has resulted in most instances the ability of the patient to return to a more useful and productive lifestyle without the burden of disabling pain or side effects.

A patient in chronic severe pain regardless of whether it is from a malignant or nonmalignant cause deserves to be rendered pain free; however, it is often clinically impossible to treat the etiology of the pain effectively. At this point the use of the modified release opiate analgesics becomes the most practical approach to treatment for these individuals. Having watched and listened to the media hype over this particular drug, it is my hope that the FDA would not implement or recommend policies that would

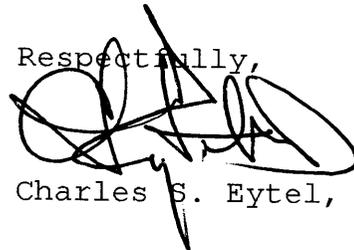
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hamper the patient's ability to legitimately have these agents prescribed by their physician because they have been a significant improvement over the nonmodified release opiates.

About twenty years ago Darvon Compound® was being used recreationally for which the pharmaceutical company, Lilly, was ultimately able to engineer a "fix". It is my fervent hope that a similar "fix" will be found for OxyContin® by Perdue Frederick through research and development. But until this occurs the stigmatization for chronic pain sufferers and further bureaucratic regulatory restrictions for these modified release opiate analgesics is not the answer. Instead, rely on physicians' judgement in determining the patient's needs through the use of clinical guidelines. Physicians are not making drug addicts out of chronic pain sufferers as most are desirous of reducing their drug requirements. We are genuinely trying to provide our patients with a means to render them comfortable with whatever the state-of-the-art available. With careful patient selection, education and counseling it is possible to prescribe these modified release opiate analgesics without more regulations. Physicians can utilize careful accurate prescribing with appropriate documentation to titrate dosages and thus reduce the risks of misdirection of these agents. When a problematic patient occurs, and they are usually quickly identifiable, they just do not get these agents prescribed for them.

Thank you for your consideration.

Respectfully,



Charles S. Eytel, M.D.

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