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August 14, 2001

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

Dear Ms. Topper:

I am writing to share my concerns and experiences as a certified hospice nurse, with advanced training in pain management, regarding your upcoming hearing, "Docket 01N-0256 Use of Opiate Analgesics in Various Patient Populations, including Pediatric Patients, etc."

I have been pleased to note on your website the variety and quality of comments you have already received. I will be unable to attend the hearing, so I request that this letter and my two (2) enclosures be considered by your staff, and that these materials be included in the public record of the hearing.

Popular media and politicians have recently exploited the existing "opiophobia" in our country which has increased fears of "an epidemic of prescription drug abuse". However, the only real, documented epidemic related to opiates is the public health crisis caused by the chronic undertreatment of pain. According to reliable estimates by national and international pain management experts there are 50 million persons in this country needlessly suffering chronic pain every year. They are the "non-combatant casualties in the war on drugs". Their pain has enormous social, economic, and spiritual, as well as physical costs.

Clinical research and experience has shown that up to 90% of this pain can be substantially, if not completely, relieved, using simple interventions including the use of carefully managed opiate medications. I believe that failure to treat pain when we have the knowledge and resources to do so is morally and ethically equivalent to torture.

The problem of diversion and abuse of prescription opiates is not related to one specific drug or form of drug, but rather the base rate of addiction in this country. I've worked in oncology and hospice and palliative care since before the approval of "OxyContin", and I well remember the changing patterns of "brand name" popularity in opiate drug diversion and abuse. Other drugs, and other forms and routes (of administration) -- even fentanyl patches -- have been popular. It is also well to remember that prescription drug abusers typically use several drugs together, often with alcohol. To blame one drug is not only unfair, it is inaccurate, and even inflammatory -- and contrary to the public interest.

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I am enclosing two letters written here (in Connecticut) in response to the public and private effects of the popular hysteria surrounding the diversion and abuse of "OxyContin": (1) from the Attorney General, Mr. Richard Blumenthal (with accompanying press release) and (2) my letter in response to the Attorney General. As the incoming chairperson of the Connecticut Cancer Pain Initiative I will be part of an interdisciplinary group (nurses, physicians, and one pharmacist) that will meet with the Attorney General's staff during the last week of August.

Qualitative judgments re. the "type" of pain are inappropriate, and counterproductive. I urge you to consider a more holistic model. I also urge you to consider the data that demonstrate that pain is experienced throughout the lifespan, and that opiate medications (alone) have been proven safe and effective in the treatment of moderate to severe pain throughout the lifespan.

I learned my most critical lessons about pain management working with young patients who were suffering the terrible pain of sickle cell crises: lessons regarding assessment (believing the patient's report of pain), tolerance, and pseudoaddiction. Research and extensive clinical experience has shown that non-cancer patients (with pain) are at the greatest risk for under-treatment of their pain, especially the elderly and those who are cognitively impaired/unable to report their pain. Please remember them in your deliberations.

I wish you and your colleagues well in your efforts on behalf of responsive and responsible pain management. Thank you for your consideration.

Yours sincerely,



Jeffrey C. Mendenhall, RN, BSN, CRNH
Clinical Supervisor, The Connecticut Hospice, Inc.
Home Care Department, Branford, CT

Enclosures

cc: The Honorable Tommy Thompson,
Secretary, Department of Health and Human Services