

September 15, 2001

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

Re: Docket Number 01N-0256

Dear Ms. Topper:

Thank you for the opportunity to submit this statement to the Food and Drug Administration Anesthetics and Life Support Drugs Advisory Committee regarding the medical use of opiate analgesics in patients with chronic pain of nonmalignant etiology, including pediatric patients.

I am writing to share with you my own personal experience as a chronic nonmalignant pain survivor, because, while my story is not unique, it does illustrate the extraordinary impact that proper pain management can have on improving the quality of life of a patient dealing with chronic, intractable pain.

First, allow me to "categorize" myself, as there are many different groups of patients, each with their own issues. I have Primary Lymphedema; a congenital form of lymphedema, which began to manifest itself in its present form about three years ago. By definition, lymphedema is a dysfunction of the lymphatic system of the body, which occurs due to either surgery, trauma, or, as in my case, genetically. The symptoms are profound, painful swelling, either in the extremities or, again, as in my case, all over the body. I also have fibromyalgia, which has been "adopted" by the American Rheumatological College, as a diffuse, painful neuromuscular syndrome, affecting multiple systems in the body. Finally, I also have been diagnosed with CFIDS, (Chronic Fatigue Immune Dysfunction Syndrome), another "odd" illness, with daily, flu-like symptoms. The sum total of these various illnesses that plague me is that by 1996, I found that I could no longer work, at all, though I tried to return a number of times. There are an estimated 8 – 10 million people who suffer from FMS (fibromyalgia). These syndromes affect middle aged women, primarily, and while not everyone is wheelchair bound, many have had to stop working due to the pain.

Once I stopped working, my days were dictated by intractable pain that over-the-counter medications could not touch. I am more fortunate than many others who share my diagnosis. I am a registered nurse and I am able to utilize my knowledge of the system in order to maximize my approach to pain management. Despite my familiarity with all of this, my road to obtain some sort of livable quality of life has been a tortuous one. I tried everything from physical therapy, multiple medical specialists, numerous ancillary drugs (non-opiate), alternative therapies, acupuncture, just to name a few of the avenues I pursued.

Yet, despite my efforts, I was bedridden for several years in pain. Until several months ago, I did not drive for almost three years.

Fortunately, two years ago, I found a compassionate healthcare practitioner; a doctor who believed in the use of opiate medication for nonmalignant chronic pain. Thank God! It was the answer to my prayers. Although it took us almost a year and a half to find the right combination of medications, I am pleased to report that I am now living the very best I can, with my pain no longer the primary symptom of my illness.

I am the recipient of a Medtronic Morphine pump, with Methadone for "breakthrough" pain. One of the greatest arguments against the use of opiates for chronic pain is the fear of addiction. This method totally eliminates that concern. The pump is computer generated and I have no access to the controls; those are preset by the doctor. The beauty of this device is that it is able to deliver the medication at a rate that is 1/300<sup>th</sup> the equivalent oral dose, without all the usual accompanying untoward side effects. Occasionally, I am still troubled by "nerve" pain, so for that, I may take 10 mg Methadone. The overall result is that I have gone from being bed-bound and wheelchair dependent to being able to actually drive a car! I am able to walk with a can and although I do still occasionally use my wheelchair for long distances and must spend some time in bed with my legs elevated, my quality of life has improved tremendously. I am able to participate in activities that I haven't been able to enjoy for quite sometime

Chronic pain is rarely considered to be life threatening, but untreated pain is a common predictor of suicide. It is also a leading cause of disability and suffering among patients. In the course of providing compassionate, humane medical care, health care providers should alleviate the suffering caused by chronic pain using the most effective medically indicated means.

I would like to encourage the FDA Anesthetics and Life Support Drugs Advisory Committee to recommend the use of opiate analgesics when medically indicated to alleviate chronic pain conditions.

Sincerely yours,

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