



The National Foundation for the Treatment of Pain

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August 8, 2001

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

re: Oxycontin Hearings

Dear Ms. Topper:

I am writing on behalf of the National Foundation for the Treatment of Pain. The NFTP is a not-for-profit-organization created to serve intractable pain patients, their families and their physicians (www.paincare.org). Over 1000 pain patients from every state in the Union belong to the Foundation.

Based upon estimates by the American Medical Association and the National Institutes of Medicine, there are approximately 17 million intractable pain patients in the United States. In 1996 there were approximately 290,000 prescriptions for oxycodone. In 2000 there were approximately 5.4 million prescriptions. The growth in the number of prescriptions correlates precisely with the growth of recognition of the need for legitimate pain treatment.

If the proposed quota of oxycodone is reduced as suggested by the DEA, barely 5% of the legitimate medical need will be met. In human terms, it is likely that 2 million current patients would not be able to legitimately obtain the opioid medication that they need to maintain a reasonable quality of life. This would completely subvert the announced policy of the DEA, itself, the Veterans Administration, the National Institutes of Health, the American Medical Association, the Joint Commission on Accreditation

of Health Care Organizations and 50 other national organizations protecting intractable pain patients.

Ironically, as this proposal is being made, far more serious than the relatively few drug abusers who abuse these medications and suffer serious or even mortal complications, are the millions of un-treated, mis-treated and abandoned pain patients who currently do not receive adequate care. The NFTP daily receives dozens of pleas for help from legitimate pain patients. Consider the following, which is typical of the case histories we receive:

"I have osteonecrosis in both hips. Total hip replacement of the right hip in 1999, bilateral core decompression of both hips in 1998. I live in West and I have been disabled since 1991 for Multiple Sclerosis. Due to heavy doses of steroids I developed osteonecrosis. My Internal med Dr. currently prescribes Darvocet which I take 2 q 4-6 hrs prn. I average 4-6 tablets a day with very little relief. My orthopedic surgeon won't address my pain and I went to a Pain Management Dr. He gave me 10 oxycodone and said that was all he could do and if the pain was this bad I needed to have the other total hip replacement. I feel like a dog chasing it's tail. The pain is not constant and I'll have a break sometimes for a day but then I take a step and practically fall down from the pain. I have "hoarded" those oxycodones since early March and have 3 left but by the time I take one the pain is so bad it doesn't help much. I never miss an appointment and my ortho doctor says to wait on the total hip replacement as I am only 44 and can't walk down the street. I finally have an appointment with another ortho in M..... on June 8th. Osteonecrosis is rare and my Dr. doesn't even know what stage my hip is in. The other one was collapsed when I went to his office sobbing before he did it. He planned on only replacing the femoral head and didn't do a MRI and when he got in found so much damage that he had to do the total hip replacement. I know I'm repeating myself but I am so frustrated with this pain and it has gone into my knees too and my Dr. doesn't believe that it can go to other joints. I pray that the Dr. that I see will at least do the MRI's to see what it shows. I need help with this pain and if I can research this disease then I would think

that an orthopedic surgeon could too. I hope you have a name of a pain clinic somewhere from M..... to N..... who will address this pain. I live almost halfway between either city, 110 miles. The Dr.s that I have been dealing with are in J....., T... which is 25 miles away. Thank You S.B. of Tennessee.”

Consider another patient’s plight:

“I have been a pain patient for a little over 11 years. I have been told that I was a drug seeker, an addict and a couple of other names to say the least. I suffer with migraine and cluster headaches. Every day for the past couple of years I’ve suffered these excruciating headaches. I can go for months without relief. I’ve been from doctor to doctor to Doctor and I can tell you some real horror stories. I am glad to see that someone is finally trying to do something about getting relief for people with pain because it is almost impossible to find a doctor who is willing to help –if not impossible. I have been to the point where the only option was to end my life, and I thank God for my family and their support because that is the only reason that I am still on God's green earth. So thank you for trying to help. Every day for the past couple of years I've suffered with these excruciating headaches. I can go for months without relief. I am glad to see that someone is finally trying to do something about getting relief for people with pain because it is almost impossible to find a doctor who is willing to help. So thank you for trying to help. K.Y. of Florida.”

Every day the NFTP web site averages 5,500 hits and the Foundation receives hundreds of letters like these concerning every conceivable cause of intractable pain. A significant percentage of intractable pain patients resort to suicide each year. Commonly intractable pain patients resort to alcoholism in a desperate search for relief. In 1997 the American Medical Association declared inadequately treated pain to be one of the major problems in American medicine. This view was echoed by the Joint Commission on the Accreditation of Health Care Organizations (JCAHO) in requiring all accredited organizations to treat

pain as a fifth vital sign. In contrast, the legitimate and effective treatment of pain is life-saving:

"I am able to do things I could no longer do. I went on a vacation with my family for the first time in 15 years! I am able to drive; I am able to work in my garden for the first time in years. Using the Oxycontin I have been having productive weeks in my business for the first time in years. I am able to work without feeling that I am going to die from pain. I had a good week and I=am able to work for more than an hour. I had been worried about my wife for years now. My pain had turned our life upside down. From overboard physically fit I turned into a physical wreck. She had never worked outside the home in 25 years of marriage. Now she has to try to help me run the business. My son is extremely upset, too. He has severe learning disabilities and is in special school. He is terrified I will commit suicide. I was definitely suicidal from the pain when I started treatment. I feel so much better with the pain under control. When you hurt that bad you can=t imagine anything worse. Yesterday I went all day without pain for the first time in 15 years. It is a Godsend."

The National Foundation can present a thousand patients to provide irrefutable testimony as to the life-saving relief that pain medications, particularly long-acting oxycodone (Oxycontin), provide. Denying that relief to them because of the addictive and drug-abusing behavior of a tiny fraction of the populace would be murder, by federal regulation, of the totally innocent. In short, the problem in the United States is not the excessive use of oxycodone and Oxycontin. Abuse is a minor problem compared to the millions who go untreated, under treated, mistreated and abandoned. Guns cause a thousand times more injuries and deaths than Oxycontin, yet gun availability is not restricted. Gasoline sniffing is epidemic in some urban areas, yet gasoline is available universally. The same is true of spray inhalants. The incidence of morbidity and mortality from alcohol is astronomical compared to Oxycontin, yet it remains legal and universally available.

The proposal to limit the medical availability of oxycodone is not a rational approach to the problem of diversion and abuse of these medications. To the contrary, promotion of the training of all American physicians in the recognition and effective treatment of pain will lead the way to the minimalization of prescriptive abuse of these medications. In the alternative, restriction of opioid supplies will accomplish nothing more than the creation of yet another drug franchise for organized, international crime.

We implore the federal government to withstand media-fanned hysteria and to support the legitimate, life saving treatment of every intractable pain patient, and the training of every physician in the recognition and effective treatment of intractable pain.

We sincerely appreciate this opportunity to defend the legitimate needs of those who suffer intractably. For pain patients, their families and their physicians,

A handwritten signature in black ink that reads "J.S. Hochman MD". The signature is written in a cursive, flowing style.

J.S. Hochman, MD

Executive Director

The National Foundation for the Treatment of Pain.