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To KIMBERLY TOPPER
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RE: HEARING ON SEPT 13 + 14

8-16-01

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

Dear Ms. Topper:

This letter concerns the upcoming FDA Hearing, September 13 and 14, being held to determine whether or not to continue treating nonmalignant, chronic pain patients with opioid analgesics, and to make inquiry into abuses of time-release opioid medication.

First, I should explain who I am and my interest in this. I am a 56 year old retired Los Angeles Police Department Detective. I am living on a medical pension due to debilitating, nonmalignant pain, that stems from injuries sustained in the line of duty. I also hold a Masters of Business Administration Degree from Pepperdine University and a Bachelor of Arts in Sociology. Because of the pain from which I suffer, I have been unable to use my education or the body of knowledge gained over a lifetime of unique experiences. Instead, I live on a medical disability pension which provides only a fraction of my potential earnings. For what it is worth, I am an expert on chronic pain and the way in which it is treated in the U.S.

From 1972 to 1974 I served on the Justice Department's Office of Drug Abuse Law Enforcement (DALE) Task Force. Later, after the DEA was formed, DALE became the DEA Task Force. There were originally 300 of us in offices throughout the U.S., all hand picked investigators from local police departments and federal agencies. In Denver, where I worked, we targeting heroin sales, exclusively, at the street level. I made numerous heroin seizures and undercover cases against heroin peddlers. As a result, I became an expert witness in cases involving the use, sale and transportation of narcotics. Throughout my 23 year law enforcement career, I was constantly exposed to the effects of illicit narcotics use.

I have academic training in the disciplines of sociology and psychology, and their training pertinent to individual and social effects of narcotic usage. Additionally, I attended numerous training programs sponsored by federal and local law enforcement agencies.

After secretly struggling with pain for several years, I eventually collapsed and was taken to the hospital emergency room twice during the last month in which I worked. In 1990 and 1991, I underwent two cervical surgeries in which three disks were removed from my neck and the four adjoining vertebra were fused. In 1999 I underwent surgery on two disks in my lower back. The surgeries only alleviated some of my pain, and they caused further complications of their own.

The disks directly adjacent to the areas that were fused will also collapse, just like a row of dominos falling. I was told that eventually the pain will become too great to endure. Until Oxycontin (a time released opioid) was prescribed, nothing else worked for long. It relieved much of my pain and returned degree of function to me.

Not everyone responds to these medications in the same manner, and it's important to recognize the vast difference between many of us. I am one of an unfortunate number of individuals who have a naturally high tolerance for Central Nervous System Depressants. Short acting opiates only last up to two hours with me but last up to six hours for some other people. Oxycontin is advertised as a 12 hour medication, but in reality only lasts a maximum of 8 hours in most pain patients.

Insomnia is normal in chronic pain patients. Time released opiates are a necessity if we are to sleep at all. It takes me at least two hours to fall asleep. If I used regular opioids, they would usually wear off before I could fall asleep, and if I were able to sleep, when the medication's effect wore off, I would be awakened almost immediately, because the medication's pain relieving effects would have worn off. It's not something that I can just "get over." The problem is here for as long as I live, and time-release opioids are the only thing that have helped.

In the event someone mentions the fact that other long lasting treatments are available, I will tell you that one size does not fit all. They are available as are extra wide shoes, but I require a narrow width. One alternative is implantation of morphine pumps. The thought of having a hockey-puck sized morphine pump installed in my abdomen is a horror! It's medical fact that people often suffer from scarring caused by the installation, pumps fail by leaking or failing to administer the proper dosage, they cause additional trauma in falls or other accidents, cause water retention, elevate blood pressure, etc. It's a barbaric practice often furthered by doctors who are afraid of having the DEA question their prescribing practices.

Another alternative, transdermal patches, quickly cause elevated opioid tolerance, require increasingly higher dose sizes within a few months and soon are not effective at any strength. In any event, the patient is the one who knows whether or not they need to be medicated, how much and when. Devices designed to administer medication at certain times are not the answer for people who's attacks of pain come without warning as to severity, duration or time.

I've seen magazine articles suggesting that it's commonplace for people to commit suicide by ingesting opioids. That's hysterical nonsense! It exists, but in over two decades as a police officer in some of the busiest, most crime ridden parts of our country, I have never seen one intentional suicide by opioid ingestion. I have seen countless cases in which someone overdosed by mistake, but usually they only became quite sick and did not die. For those choosing to die, there are a number of other drugs that will do the job. For example, tricyclic antidepressants are readily available and some of the most deadly of known substances. There seems to be no outcry to control them.

I don't believe that we have suddenly developed concern for an occasional overdose victim either. News broadcasts claim that approximately 100 deaths have been caused by accidental overdose with time released opioids. While those numbers are open to question, it's recorded medical fact that approximately 110,000 patients are killed in hospitals every year because someone prescribed the wrong medication! Not caused by a staff member who put a decimal point in the wrong place, or a nurse who mistakenly administered the wrong medicine, but doctors who prescribed the wrong medication and killed patients under hospital care. An additional 100,000-200,000 unwarranted deaths a year are also alleged to take place in hospitals, deaths for something other than what the patient was admitted and being treated for, deaths due to lack of attention. A couple of years ago there were numerous newspaper articles reporting the above deaths, but the AMA is a wealthy organization to tackle.

Speaking of the AMA, just why is it assumed by so many people that doctors are experts on pain? I've interviewed many doctors and found the majority of them to be woefully ignorant, even many of those who claim to have received special training in pain and it's treatment. Engaging in an academic exercise and interviewing people in sterile, windowless rooms, does little to further a doctor's knowledge into pain and it's effects. I, on the other hand, have learned my lessons in the trenches first and have done the research by necessity.

A big problem faced by pain patients, like me, is the ignorance surrounding opioid use. Thirty years ago in psychology classes, we differentiated between drug addiction and drug dependence. The two are not related. In a nutshell, addicts are after a "high" which is something almost universally absent in those who take opiates for medical reasons. People like me do not seek drugs; *we seek relief!* We become physically dependant on the substance, meaning we become very sick if the supply is suddenly removed, but we are not addicted to it; we would not take it if we did not have a physical condition for which it provides relief. I've used opiates for years and have never been "high."

Before someone begins wringing their hands about physical dependance, realize that doctors cause it in thousands of patients with other substances. The doctor who placed me on Temormin, a beta-blocker, was not concerned with my dependance on the medication. If someone stops taking that drug, they can die! How's that for physical dependence? The physical dependence facts of beta blocker therapy were not disclosed to be beforehand, but it also happens with many different medications and hundreds of thousands of patients. I read a hysteria-type story on beta-blockers a few years ago, but it did not capture the imagination of the media like "narcotics" does.

Medicine cures very few diseases, but they do treat hundreds. There is no cure for what I have, but there is no reason to deprive me of comfort while I live. Unabated suffering crushes too many lives to justify tinkering with those victims of chronic pain for whom current treatments provide relief.

Why are chronic pain patients being harassed? I was a detective too long to swallow the premise that someone is suddenly concerned with my welfare. Other interests are at work here, and they

are not hard to discern. First of all are the doctors who, just recently, being called to answer for not adequately controlling their patient's pain. Long ago the medical community succeeded in gaining control of opiod medications, but have been highly reluctant to allow pain suffers to have access to them. Almost anyone who suffers from chronic pain can recount numerous instances where doctors have told them lines such as, "You'll just have to learn to live with it "

My experience tells me that when ordinary people resort to the courts, it is usually because they have tried all other means available to them and failed. In these cases, they're desperate and certainly not "drug seekers." Only recently have medical establishment victims begun to take doctors to court because the doctor failed to provide adequate pain relief.

Why did I arrive at the conclusion that doctors are one force behind this attempt to deprive us of opiates? Motive. I spoke with a doctor who I know, right after learning of the upcoming hearings, and I asked him what he thought was behind it. He seemed to be thinking out loud when he answered, saying, "It's crazy. Patients are suing their doctors for not providing adequate pain relief..." It was almost like he had read the words, and certainly clarified the situation for someone who was a detective for almost 20 years. **If one or more of the government's regulating agencies prohibit doctors from prescribing opiates, the doctor can not be held civilly liable for not providing adequate pain relief.**

Those involved in the War on Drugs also stand to gain politically from a perceived "win." Presently a number of people question the validity of how the "war" is being waged, some even calling it a failure. If a new enemy were paraded out, as though it had been previously hidden among us, and accused of causing countless deaths, a crisis hungry media will be sure to respond. Future funding will be available, jobs will be secure and no one will question their motives.

I briefly mentioned the media, and they stand to win no matter who looses. Different broadcasting networks have run horror stories, as have radio talk shows, about the terrible "synthetic heroin," Oxycontin. Almost everyone has learned the name of my medication, thanks to the press. What they do not know is that it is the reason that I am alive today.

I have a doctor, an outstanding and knowledgeable pain anesthesiologist, who performed extensive evaluations on my prior to taking me as a patient. He waded through a stack of medical background material several inches thick. I signed a contract with him in which I agreed to submit to drug testing, promised not to use medication prescribed to others, promised not to use illegal drugs, divert mine, etc. I agreed to obtain his permission before filling a prescription, from another doctor, if it is for a narcotic or other central nervous system depressant. Any violation can, at his discretion, cause me to be dropped from his treatment. He spends a minimum of 30 minutes once a month with me, discussing my treatment and latest developments.

I prepare a written progress report once a month for my doctor. In them I report any unusual symptoms, especially those that might be related to medication. I elaborate on the ways in which I am attempting to further my physical rehabilitation, and I advise him of changes in my other

prescription medications or dietary supplements. Neither of us is able to more reliably guarantee that we do not violate any laws, rules or ethical concerns.

What do we do, concerning those who die because they bite pills in half, chew them, grind them up and inject them? Doctors and pharmacist tell patients not to do those things or they could die. The drug companies have the same information in the package insert. Nature has a way of insuring that a species remains strong. Those that are too stupid to survive usually do not remain around long enough to contribute to the gene pool. Like it or not, some are just "terminally stupid," and can't be saved regardless of the enormous expenditures of time and money to preserve them.

As for diversion, someone will always do it when they see a way to make a dollar. Inner-city neighborhoods have individuals who traffic in all medications, for all illnesses. They make it clear they are not doctors but are simply operating out of their residences, trading in stolen goods, cash and drugs. Interestingly enough, in most instances, they seem to be as effective in their treatments as conventual medical practitioners.

I've often envied those with terminal malignancies, because they can see an end to their suffering. Chronic pain comes and says, "I'm here, and I'm not going away." It's my first thought each time I awaken and is first to greet me with the new day. Uncontrolled, it rides me all day and all night, gnawing at my very core. Uncontrolled, it interprets the world for me telling me what I can do and what I can not, it alienates my associates and eliminates relationships.

I listen to other people's plans, unable to make any of my own, except for those that can be changed at the last minute, thankful that I have a medication that will allow me to make small plans.

I fear family vacations, because at any moment "breakthrough pain" may rob us of our time together. I know what it's like to be asked not to go somewhere with my family, because no one wants to be with someone in pain. It's unbelievably lonely, but they have a right to lives too.

Oxycontin, a time released opiod, is my only defense against chronic pain. It's a world that you never want to enter.

I apologize for not being able to edit this, check grammar or spelling, but the pain of sitting so long will not be denied.

Yours truly,



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