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Ms. Kimberly Topper
Center for Drug Evaluation and Research (HFD-21)
Food and Drug Administration
5600 Fisher's Lane
Rockville, MD 20857

Dear Ms. Topper:

According to the *Federal Register* "notice of hearing" May 3, 2001, the committee intends to discuss the medical use of opiate analgesics at hearings June 14th and 15th. The published agenda suggests that the area of concern is the "risk to benefit ratio" of the extension of opiate treatment into the area of chronic nonmalignant pain, particularly with reference to abuse potential, diversion and addiction issues.

My name is Patrick Clary. I am a physician graduate of Georgetown University School of Medicine and have served in various positions within three different hospices since 1988. I am Board Certified in Family Practice, and in Hospice and Palliative Care, and currently work as the half-time Medical Director of Seacoast Hospice, the only nonprofit freestanding hospice in New Hampshire. In addition to hospice work, caring for people at the end of their lives, I continue to own and direct a family practice providing primary medical care to 25,000 citizens of New Hampshire and Maine. I also act as the medical director of the largest Nursing Home in my home county. I have been in practice for 21 years. Before attending college and medical school I served in the US Army, trained as a medical corpsman, and spent the year of June 13th, 1969 through June 12th, 1970 as an infantry medic in Vietnam. I was decorated modestly and honorably discharged with the rank of Specialist 5th Class.

I began hospice work in 1988 because it was necessary rather than because of any intrinsic interest the work held for me. Our patients were dying in pain and it was clear that was absolutely wrong. The therapeutic solution was not rocket science but the straightforward use of one of the oldest groups of medications used in Western medicine: opioid analgesics. Yet over and over again I have seen the same barrier to effective pain treatment at the end of life. This barrier is fear. Doctors still tell me they are afraid of the Drug Enforcement Agency, and they tell me they are afraid their patients are going to "get addicted." Half of all patients dying in good tertiary care hospitals continue to die in pain, and as many as 80% of nursing home patients die in pain. This is so clearly wrong that I don't wish to belabor it. I am certain that it is not your intention in formulating and enforcing regulations to increase the proportion of people dying in pain. I want to request that you also consider such unwanted consequences as you consider rulemaking in this area.

News media suggest that the FDA is considering the limitation of opioid prescriptions to specialists in pain management, and that chronic nonmalignant pain may be excluded from opioid therapies. My observation of this group of specialists suggests that they prefer to avoid the use of opioids for chronic pain in general.

Conversations with individuals among them suggests that fear may be a barrier in this area even for the highly trained. Economic considerations also drive treatment in the direction of performing expensive and repetitive procedures for pain relief even when noninvasive use of opioid analgesics would likely be more cost-effective. One of my colleagues in pain management once confessed to me that he knew that opioids would take care of most pain issues, "But they come expecting eight hundred dollar procedures so who am I to substitute an eighty-dollar office visit for that?"

Those of us in hospice medicine were the first to make the observation that "getting ahead of the pain" with an opioid often restored function in malignant pain. Time-release versions of these medications have allowed effective treatment without the need for dosing every three to four hours, helping in both the logistics and psychology of adherence to any pain regimen. When any pain is effectively treated with a dose of time-released opioids we often find that the dose stabilizes for months or years at a time, only increasing when the disease changes.

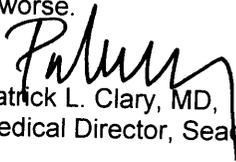
In hospice medicine we really don't depend on the distinction between chronic malignant and nonmalignant pain. It isn't always even possible to make that distinction. It is always possible to make the distinction between mild, moderate, and severe pain. We begin treatment on the WHO pain ladder with weaker medications such as acetaminophen and non-steroidal anti-inflammatories, tending toward stronger opioids for more severe pain. We do tend to use opioids more liberally in our patients who are dying. Pain in the context of approaching death is a more hopeless experience, therefore more difficult to control without opioids, and may well get in the way of unfinished emotional and spiritual work that will ease the burden not only for the dying but for their survivors.

I am not, however, proposing that you establish dying as a prerequisite for appropriateness for opioid use. Prognosis is a very difficult undertaking little taught in medical school and little studied. It's very difficult to say when a patient suffering from a chronic disease is actually dying. It is so difficult, in fact, that prognosis appears to be the most impermeable barrier to hospice care. Half of the patients in my hospice are admitted less than 15 days before death, and we only care for 20% of all of the dying even in that limited time frame. These statistics are true nationally. Limiting use of opioids will lead to unrelieved suffering among the dying even if you include hospice patients as appropriate for treatment with these agents. A vast majority of the dying never come to our care.

While my knowledge of the legitimate use of opioid analgesics comes primarily from 13 years of the study and practice of end-of-life care, I am also concerned with my practice's 25,000 patients in the middle of their lives. It's our practice policy to refer patients with nonmalignant chronic pain syndromes to pain management specialists to establish treatment plans, but I often find myself comfortable following them on opioid analgesics after therapy has been established. Even in my well-served area there aren't enough pain management specialists to follow all chronic pain patients adequately.

One of my patients with a diabetic neuropathy told me that he felt that he had gotten his life back after effective pain management with small around-the-clock doses of methadone, a shift in treatment I initiated after failure in specialty care. The effective treatment of chronic pain in the middle of people's lives is often very gratifying, though perhaps not as essential as end-of-life care.

I understand the policy concerns of those who seek to limit the diversion of opioids and the epidemic of addiction. However, when you look at what's at stake here, please consider that rules increasing the barriers to effective pain management will condemn citizens to living and dying in pain. I can't help thinking of a scene near the end of the recent movie "Traffic," in which the "war on drugs" is defined as a war on our own people. When you deliberately raise barriers to effective pain management, whatever your motives, you are making war on the most helpless of your citizens, the dying and those in chronic pain. Two and half million Americans die every year, and many millions more live in pain. I can tell you that the situation now is more horrible than anything I ever saw in Vietnam. Don't take actions to make it worse.


Patrick L. Clary, MD,
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