

Upstate Medical Rehabilitation

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Ms. Kimberly Topper
Food and Drug Administration, CDR
Advisors and consultant Staff
HFD-21
5600 Fishers Lane
Rockville, Maryland 29857

Dear Ms. Topper:

Thank you for the opportunity to send comments to your committee concerning the appropriate use of opiate medications in the patient with pain from non-malignant etiology.

I am a physiatrist, board-certified in pain management. I have been treating acute, subacute and chronic pain. In my practice, I have access to modalities including injection techniques under fluoroscopy, physical therapy, massage therapy, acupuncture as well as psychological support. I have studied the use of many different sorts of analgesic medications as well as other psychotropic medications useful in treating painful conditions. It has been my experience that there is a significant number of patients suffering from pain of non-malignant etiology who benefit significantly from the use of opiate medications.

We monitor this very closely in the office. To meet our criteria for the use of opiate medications, the patients have to have, number one, a source of nociceptive pain which we can identify. Number two, pain must be in the severe range (7-10 on a 0-10 scale). Number three, the pain must have a significant impact on their life including changes in daily living patterns, employability, sleep, recreational activities or intimate relationships. Number four, the patient must sign informed consent form in this office. The informed consent form includes a stipulation that they give up privacy regarding the use of these medicines. They may not get controlled substances from any other physician, they understand that the medication being prescribed is habit forming and potentially addicting and that they are willing to take a risk in order to improve their quality of life. Number five, for continued prescriptions of medication, they need to document improvement in lifestyle, decrease in pain and an absence of side effects from the medications.

With the above treatment paradigm, we have found many patients whose lives have been helped considerably with the use of opiate medications.

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Ms. Kimberly Topper
July 26, 2001
Page 2

There are several issues regarding these medicines which have come to everybody's attention. Number one is safety. In general, when these medications are used as prescribed, they are safe medications. There has been a tragedy in this country of multiple thousands of deaths occurring because of the use of other non-opiate analgesics and with other medications which are used to avoid opiate analgesics. As an example, there are 16 to 18,000 deaths a year from nonsteroidal anti-inflammatories due to stomach ulcers. There are thousands of deaths a year because of Tylenol use affecting livers. Tricyclic antidepressants which are used for their pain relieving ability are associated with cardiac deaths as well as deaths from falls due to postural hypotension. Seizure medicines are associated with hepatic problems and cognitive side effects. In short, the treatment of pain is fraught with risk. The risk from opiate medications used appropriately is less than the risk of using these other medications in many cases.

The second issue is that of addiction. Opiate medicines are potentially addicting but generally only in patients with a proven addiction potential. The patient who is in pain generally does not get a significant feeling of euphoria from the use of the pain medications and these medicines are not addicting in most cases. Dependency certainly does develop to them such that when the patients stop the medications suddenly, they are likely to have withdrawal symptoms. However, in my population, patients who go through withdrawal seldom show true signs of addiction such as looking for the medications on the street, attempting to use medications for reasons other than pain, or signs of injecting medications.

A third issue is that of cost. Opiate medications, especially some of the newer ones, are quite expensive. However, in my population, I often find that patients have gone from physician to physician, therapist to therapist, and MRI scan to CAT scan to myelogram, EMG, thermographic study, etc. seeking a relief for their pain. The costs involved in patient being dissatisfied with their care and in doctor shopping are extremely high and the overall cost when the patient is treated appropriately by a team approach in a single office including appropriate medications is probably much lower.

Ms. Kimberly Topper
July 26, 2001
Page 3

A fourth issue is that of diversion of medications. It is undoubtedly true that patients are diverting medications into the opiate seeking population who are using these for recreational reasons. There have been deaths from people using medications inappropriately. Practitioners need to make every effort to avoid having their medications diverted for purposes they were not originally intended. However, I do not believe that the overall number of deaths from opiates is any higher in recent years. It has only been in the last four to five years that physicians have felt that they could use these medications without fear of stigmatizing themselves or their patients and that they could use these medications without fear of legal sanction. Thus, there has been an enormous increase in the prescriptions coming out of physicians' offices of opiate medicines. Because these drugs are now widely available on the street, it is undoubtedly the case that many of the drug related deaths will come from legal substances instead of from the illegal substances which they used to be caused by. However, I doubt that there is a significant number in the overall narcotic related deaths in this country because of the availability of legal opiates instead of illegal opiates. I would suggest that there are certainly less suicides in chronic pain patients once their pain is adequately treated and less deaths in the pain patient due to the decrease in the number of people using nonsteroidal anti-inflammatories for severe pain (for which they are not intended).

On balance, I believe that the use of opiates by physicians who specialize in pain management and are trained in the use and abuse of opiate medications is very appropriate and I hope that this panel can agree with this finding. I know that the huge numbers of people whose pain has been under treated over the years would very strongly support the availability of these medications.

Sincerely,



David L. Shallcross, M.D.

DJS/tr