May 25, 2001

Kimberly Topper
Center for Drug Evaluation and Research
FDA
5600 Fishers Lane
Rockville, MA 20857

Dear Ms. Topper:

I am writing to you after hearing concerns raised by doctors in my community about proposed changes in opioid prescription guidelines by the FDA. I understand that you are chairing a meeting to address recent concerns about the use of opioids for chronic nonmalignant pain at a meeting June 14 and 15 in Gaithersburg, MD. I would like to express my opinion.

I am a neurologist and Associate Professor at the University of Pittsburgh Medical Center in Pittsburgh, Pennsylvania. I have worked as a pain management physician for the last decade, and had the privilege of working with Dennis Turk, Ph.D., who has been instrumental in the development of multidisciplinary pain management. Over the last decade, the pain community has undergone a significant policy change regarding the use of opioids for chronic nonmalignant pain. Ten years ago, patients with chronic pain were tapered off of chronic narcotics and simple analgesics were substituted. In the last several years, recommendations for more liberal use of narcotics for chronic pain patients have been endorsed and studied in research protocols. The proposed advantage to opioids over analgesics is improved efficacy and reduced organ toxicity.

As I have worked with pain patients throughout this transition period, I have had the unique opportunity of seeing the consequences to this policy shift. Problems with addiction and medication misuse have not changed significantly with the change in prescribing practices for patients. Patients with addiction problems have and always will struggle with abuse. We have not seen abuse increase in our facility as the use of chronic opioids has increased. We have always needed to maintain a relationship with drug abuse facilities, and our referrals to these facilities have not increased with increased use of prescribed opioids.

I have been fortunate to gain the clinical experience from having the privilege to follow patients as they finish school, change careers, get married, and raise children and grandchildren. This has increased my skepticism about new therapies and policies. Despite my initial reluctance to begin prescribing chronic opioids for nonmalignant pain patients, I have been very pleased to see two significant positive outcomes. One, there are fewer patients experiencing serious adverse effects from the overuse of analgesics, such as gastric bleeding and nephrotoxicity. Second, many patients have been able to return to a functional lifestyle, aided by the pain relief they are afforded with chronic narcotics. One of my typical patients experienced a major life change, aided by pain relief obtained from switching analgesics to chronic opioids. Total disability and dependence on his family were replaced with returning to college to complete a dental hygienist degree, followed by a successful career in dentistry and an independent lifestyle.

The new JCAHO guidelines have increased both interest and education in the medical community to address chronic pain. Although pain complaints rank among the most common complaint patients bring to their doctors, doctors receive minimal training in how to manage these patients. Implementation of these guidelines will hopefully assist in this long-term educational project. Lack of education has resulted in inappropriate prescribing of narcotics for some patients.

I believe that opioids do have a role in the management of chronic pain for some patients. Patients need to have a pain diagnosis, goals for use of narcotic (e.g., improving functional ability, reducing dangerous overuse of analgesics), and appropriate doctor follow-up. Doctors need to monitor outcome for pain treatment, as well as compliance to therapy. These are the same basic guidelines of good medical practice that are used for treating all chronic health problems, including heart disease, high blood pressure, diabetes,

etc. I strongly believe that the treatment of pain with opioids should be no different than the treatment of other health conditions. Adding excessive restrictions or requirements confers to opioids "special/magical" properties, suggesting to both doctors and patients that the same good practice guidelines used for other health conditions and medications do not apply to opioids. I believe this will actually increase inappropriate use of these medications. There are no guidelines that will prevent the most conscientious doctor from occasionally being misled by patients. Doctors will always need to monitor their patients for the overuse or misuse of any habituating medications. Although this increases the burden of patient care for doctors, the benefits obtained by the majority of patients who appropriately use prescribed opioids clearly outweighs the inconvenience.

The Federation of State Medical Boards has a set of recommended guidelines for the treatment of chronic nonmalignant pain available on their web page (fsmb.org). These are excellent guidelines that incorporate the same good practice guidelines doctors are already using for treating other health conditions. I would encourage you to review these guidelines. They are also consistent with guidelines that are already in use by several states.

In summary, opioids can provide a safe, effective therapy for some patients with chronic pain. They are not a panacea to correct all of the symptoms of chronic pain, but they can provide useful adjunctive therapy. Most doctors should be capable of managing these medications for the typical patient with chronic pain. When patients do not comply with therapy or there are concerns about addiction, patients may need to be referred to pain specialists or abuse counselors. I am concerned about the message received by both patients and doctors when opioids are raised to exceptional status, with prescribing guidelines that are unique to these medications.

Thank you for allowing me to express my opinion. I wish you the best of luck in addressing the complex problems associated with the management of chronic pain patients.

Sincerely,

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