CAROL P. CURTISS, RN, MSN

CURTISS CONSULTING

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Food and Drug Administration, CDER
Anesthetic and Life Support Drugs Advisory Committee
5600 Fishers Lane
Rockville, MD 20857

Dear Advisory Committee Members

My name is Carol P. Curtiss. I am a registered nurse with a master's degree in oncology nursing from Yale University and a past national president of the Oncology Nursing Society (1992-1993). For the past 23 years, I have devoted my professional life to improving the care of people with pain. I've had the privilege to educate health care professionals and the public in forty-three states in the U.S. and 10 other countries. I've authored more than 20 publications about pain in professional journals or texts. Providing effective, safe and competent pain care and educating others to do the same is my professional passion.

Over the years, I've seen, first hand, the destructive effects of pain on individuals and families. People with pain often tell of the agony of unrelieved pain, of searching desperately for someone to manage pain well, and of the helplessness and hopelessness that accompanies persistent unrelieved pain. I've seen unrelieved pain destroy lives, families, and undermine the will to live. I've also seen the tremendous gratitude expressed by people when their pain is well managed and they once again are able to live a meaningful life.

As you deliberate the medical use of opioid analgesics in various populations and the risk benefit ratio of extending opioid treatment to these populations, I ask you to carefully consider current information about pain, pain transmission and treatment, and the vital role of opioids in managing severe pain in all people with pain, regardless of etiology. Both the science and the clinical practice of pain management have changed significantly over the past several years – much of what most of us learned during our careers is now outdated and is replaced with new information.

For most people, severe unrelieved pain of all types is rarely managed effectively without a comprehensive plan that includes the use of opioids. Opioid analgesics have been the cornerstone for managing moderately severe to severe cancer pain and acute pain for many years. Opioids also play an important role in managing chronic non-cancer pain that does not respond to other interventions. For individuals who remain in severe chronic non-cancer pain in spite of other interventions, opioids often provide the only

73 James Street Greenfield, MA 01301 (413) 774-5238 FAX (413) 774-3762
ccurtiss@shaysnet.com

hope for improvement. Competent clinical practice guides the use of opioids in all populations. When patients are carefully evaluated and routinely followed, the use of opioids as part of a pain plan can mean the difference between moving about comfortably, returning to work (for children, returning to school), relating well to others and improving quality of life compared to an existence ruled by pain. Please also consider the following:

- **Pain is unique, an extraordinarily complex problem, and a different experience for each person.**

  Each individual responds in different ways to pain. However, physiologically, persistent unrelieved pain affects every body system, including immune response, and takes a tremendous emotional toll on the person in pain and their loved ones. Pain pathophysiology is very complex – the science of pain and pain transmission is evolving rapidly, giving us more insight into the negative effects of uncontrolled pain in all people. Clinically, infants and children with unrelieved chronic pain often are listless and withdrawn from social interaction. Unrelieved pain in adults with all types of persistent pain often causes depression and the need to question the value of life. David Morris in *The Culture of Pain* (1991) reminds us that because we have the means to manage most pain and studies continue to show under-treatment of pain, "Failing to treat pain effectively brushes perilously close to intentionally inflicting it."

- **Effective pain management requires a comprehensive, interdisciplinary approach.**

  The complexity of chronic non-cancer and cancer pain and individual responses to pain interventions frequently requires interdisciplinary expertise and a variety of different intervention, either alone or together: medications, non-drug interventions and sometimes, technology. Because every person responds differently to pain and pain relief strategies, careful, comprehensive, and on-going evaluation is vital.

- **Effective pain management requires a variety of strategies specifically selected for the individual.**

  Each person with pain requires different strategies to manage pain, even if pain seems similar to that of others. The key to effective pain management is to select a variety of strategies specifically for one individual based on thorough clinical evaluation of pain and the effects of the pain plan on reducing pain, increasing function or improving quality of life.

  Medications that work for one person may be entirely ineffective in another individual with similar pain. There is no single "magic bullet" that will relieve all pain in all people. In fact, one of the keys to effective pain management is a plan based on individual needs and individual responses of the person with pain. A "cookie cutter" approach will not work. In order to manage pain well, clinicians must have access to a variety of non-drug and pharmacologic interventions, and design a plan that meets the unique needs of each person.

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- **Opioids are vital for managing severe pain of all types.**

  Opioids are necessary to manage severe pain in most people. They are the key for managing nearly all severe nociceptive pain, regardless of cause, and are sometimes effective for some, but not all, severe neuropathic pain. I've seen improved function and increased quality of life in people taking opioids for severe arthritis pain, back pain, cancer pain and other non-cancer diagnoses.

  Maintaining a steady serum level of analgesia sufficient to manage most of the pain most of the time is the basic goal of pain therapy for people with persistent pain – in other words – obtaining maximum relief, with minimal side effects, in a simple plan to follow. Long acting oral morphine and oxycodone provide clinicians a way to maintain steady serum levels without requiring the person to interrupt sleep nightly to take medications or to focus on medication schedules during the day. This alone, improves quality of life for many. Limiting access to this family of medications or to long acting formulations will cause people in pain to suffer needlessly and decrease clinician's abilities to manage severe pain effectively. Non-drug interventions, invasive procedures, non-opioid analgesics, and other adjuvant medications, alone or in combination with one another, simply can not do the job for all people.

- **Most people who take opioids for pain control are very serious and careful about their medications and their pain plan.**

  In my experience, people are quite responsible when taking opioids for pain. They take their medicines as prescribed (or more often, less than the amounts prescribed) and keep them safely stored. In fact, many are afraid and reluctant to take needed medications when pain is severe due to their own fears and concerns. The current media blitz about long acting oxycodone has terrified many patients with pain. Just this morning, a patient told me he was going to ask his doctor to give him something "less dangerous" because of an article he'd read in the newspaper. For this man, the medication was effective; his dose had been stable for more than 4 months; he took his medications as directed; did not experience unmanageable side effects; and had improved function. Yet, he was frightened to continue this effective regime. Like this man and many others I've cared for, pain patients do not snort, crush and inject or sell their medications. They carefully follow directions and consistently ask about their concerns for taking "strong medicines". Patients are also erroneously afraid to "get hooked," – they've heard from neighbors and the media that the medications aren't "safe" and yet they see the difference the medication can make in improving their quality of life.

  Sometimes lack of knowledge on the part of health care professionals makes it more difficult. One patient told me she felt as if she were a criminal because she was required to obtain weekly refills for her opioid medication. Her source of pain would last a lifetime – her pain management would need to last a lifetime too. Yet, she was admonished by the pharmacist during each trip to the pharmacy that "she had to get off the meds so she wouldn't get addicted". This patient had always been totally compliant with dosing and schedules and did not have a history of substance abuse disorders. A great deal of teaching and support was needed to assure her that both published studies and clinical practice show, when medications are appropriately prescribed and taken as directed, addiction to opioids is rare in people with pain.

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- **Children continue to be under-treated for pain.**

  Studies continue to demonstrate the under-treatment of pain in children. Clinically, I consistently hear stories of unrelieved severe pain in children. For example: the mother of an 8 year old girl with a partially resected neuroblastoma related her frustrations with trying to obtain relief for her daughter. The daughter's pain was severe and interfered with her ability to play, go to school and enjoy her childhood. She spent most of the day and night in bed, limited only by pain. Her pediatrician would only prescribe acetaminophen with codeine – it did nothing for the child's relief. Eventually, the mother, arming herself with the medical literature, persuaded the physician to try an opioid – in this case oxycodone – and brought clinical information to assist the physician in dose titration. Within a few days her daughter returned to school with significant pain relief and clearly an improved quality of life.

- **While drug diversion is a significant problem in the U.S., limiting access to opioids for people with pain will do little, if anything, to change the problem.**

  Diversion of medications for substance abuse and the legitimate use of medications for pain are two distinct entities. As one prosecuting attorney states, "People with a substance abuse disorder live their lives to use drugs. People with pain use medicines in order to live their lives." Competent clinicians make every effort to follow the Federation of State Medical Boards *Guidelines for the Use of Controlled Substances to Treat Pain* and to carefully evaluate patients to try to avoid inadvertently prescribing for someone who intends to divert the medication. Limiting access to opioids for people with pain in an attempt to stop drug diversion doesn't make sense. However, assisting clinicians to learn better ways to identify inappropriate prescribing, improve assessment skills, and base care on sound clinical inquiry and judgment could help. As always, looking for better ways to deal with those individuals with substance abuse disorders and the illicit drug problem in the U.S. is important. However, in my view, restricting the use of medications in people with pain or limiting access outside clinical facilities will only increase suffering and do nothing to address the problem of drug diversion and substance abuse.

I appreciate the opportunity to comment before your deliberations and hope you support access to these important medications for people with moderately severe to severe pain, including children and those with chronic non-cancer pain who have been unable to find relief from other therapies. There are already many barriers to effective pain management. Limiting access to these medications would seriously cripple the efforts of clinicians to treat pain competently.

Sincerely,

Carol P. Curtiss, RN, MSN

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