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July 28, 2003

FDA Anesthetic and Life Support Committee
Attn: Johanna Clifford
Center for Drug Evaluation and Research (HFD-21)
Food and Drug Administration
Rm. 1093, 5630 Fishers Lane
Rockville, MD 20857

**RE: Opioid Risk Management. Docket 2003N-0294**

Dear Committee Members,

As a masters prepared advanced practice nurse with over 36 years of experience, with 25 years experience in the field of cancer care and pain management, I have significant concerns about the potential effects on patient care of a risk management program that restricts or imposes additional conditions on opioid analgesics.

Research continues to identify the under-treatment of all types of pain as a major public health problem. Clinically, I see patients who are already extremely reluctant to take opioids for pain, even when their lives are destroyed because of poor pain relief – they simply are afraid of what they perceive as "strong dangerous drugs" and are erroneously concerned about the incidence of addiction and abuse. Studies and clinical practice continues to show that addiction is rare in individuals who take opioids for pain when they do not already have a history of substance abuse disorder. The incidence of addiction for individuals who take opioids for pain is thought to be no greater than the incidence of addiction in the general population in the United States. Yet people are extremely hesitant to take opioids, frequently ask to decrease their doses, and carefully protect their medications at home.

It is vital that patients have access to appropriate medications to relieve pain. For those with acute or persistent moderately severe to severe pain, opioids are frequently the medications of choice as part of a comprehensive program to decrease pain, improve function, sleep, mood, other activities of daily living, participate in recovery, and for some, experience a comfortable death. Physicians, advanced practice nurses with prescriptive authority, and other health care providers must have the ability to prescribe opioids when medically necessary, without additional barriers to impede effective pain management.

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Therefore, I am **opposed** to any risk management program that includes the following:

1. **Additional requirements for special training/licensing in order for a provider to prescribe opioids**
    a. Pain is the primary reason patients seek health care in the United States. Primary care physicians, nurse practitioners in primary care, internists and others who see patients as primary care providers must be able to prescribe opioids when indicated for competent care. Specialists such as rheumatologists, oncologists, cardiovascular physicians, orthopedists and others also require the ability to prescribe when patients have moderately severe to severe pain. Basic education should include the appropriate use and dosing of opioids for all providers.
    b. Placing restrictions on prescribing (pre-authorization, for example) results in delayed and inappropriate pain management. In today's busy health care environment, I have seen physicians or nurse practitioners prescribe less effective medications rather than go through the pre-authorization process. Patients are the ultimate bearers of this problem.
2. **Restricting/limiting prescribing of opioids only to specialists**
    a. This will have a chilling effect on pain management for patients in pain. Health maintenance organizations and many insurers require written referral for specialty care and restrict it to problems that cannot be addressed within their networks. Pain crosses all specialties as well as primary care. This decision would limit appropriate access to pain care for many patients.
3. **Restricting or limiting prescribing to only certain patient populations**
    a. Pain is common for nearly all diagnoses. Moderately severe to severe pain of any cause is usually treated with opioids as part of the comprehensive plan of care. Restricting prescribing to certain patient populations is discriminatory without merit.
4. **A risk management plan that applies to only specific opioids (for example: extended release opioids). Any plan should be inclusive of all opioids, not specific to select opioids.**
    a. All opioids, as well as many other types of drugs, have abuse and misuse potential. Selecting only a few opioids for risk management plans or restrictive use makes no sense at all. New science shows that individuals respond to different analgesics, including opioids, selectively. In other words, what works for one patient may not work for another with similar pain. In order to manage pain effectively, a variety of medications within the same family are necessary and must be available.

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b. In addition, extended release opioids allow patients to sleep through the night, decrease the number of doses of medication per day (resulting in increased patient compliance), and provide a steady serum level that relieves pain effectively over a 24 hour period. They are key components of a therapeutic regime for all types of patients with pain.

5. **Centralization/limitation of pharmacies that are able to fill prescriptions for opioids.**
    a. This would have a chilling effect on patient access to care. I live in a rural area of Massachusetts where patients already must travel up to an hour to get to the closest local pharmacy. Centralizing or limiting access to pharmacies that carry opioids would further increase the burden on patients and their families. Requiring mail order prescription fulfillment may work for predictable medical problems, but will not work for an acute pain episode or a sudden exacerbation of persistent pain.
6. **Any risk management plan that confuses the appropriate use of opioids for pain with the separate issue of misuse, abuse and diversion**
    a. The appropriate use of opioids for pain management should not be confused with the issue of abuse, misuse and diversion. In my experience, patients and their families are very concerned about taking opioids, concerned about addiction, misuse and overuse, and require continued support and education to use opioids as part of the pain management plan. Abuse and misuse, are a very different problem than effective pain control and the two should not be addressed as if they are the same. Individuals with addictive disorders live their lives in order to use drugs. Their behaviors cause an individual to continue to use drugs in spite of personal, social, emotional and physical harm. People with pain, on the other hand, use pain medications in order to live their lives more fully. They are concerned about their health problems, often have medications left over, ask to decrease the dose and look forward to a time when they do not need to rely on medications for pain control. Clearly, the two are not the same.

In your deliberations, I urge you to be certain that those who need opioids as part of a comprehensive pain management program from any physician, nurse practitioner or other health care provider have easy access to these medications.

Reasonable approaches to improving pain management while at the same time directing the appropriate use of medications are:

1. **Mandate that new science about pain physiology and pathophysiology, the consequences of unrelieved pain, assessment of pain, strategies to use medications, including opioids, and ways to integrate non-drug interventions into a complete pain management plan be included as part of the curriculum in all medical schools, nursing and pharmacy programs in the U.S.**

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2. **Endorse the Federation of State Medical Boards document "Model Guidelines for the Use of Controlled Substances for the Treatment of Pain" (1998).**
3. **Recommend health care facilities in all settings monitor unrelieved pain and problems associated with pain management plans, including inappropriate use of medications as part of the regular Quality Improvement/Performance Improvement process with the goal of improving the treatment of pain using published national standard and guidelines.**
4. **Consider the D.E.A. program in the state of Hawaii as a possible model for looking for abuse and misuse. This program tracks patients when opioids are prescribed and looks for signs of abuse or misuse.**

Thank you for the opportunity to comment on your crucial discussion. Patients and their families have much to lose with additional restrictive rules for opioids.

Sincerely,

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