



March 3, 2005

Michele M. Leonhart
Deputy Administrator
Drug Enforcement Administration
2401 Jefferson Davis Highway
Alexandria, VA 22301

Regarding: **Docket #DEA-261**

Dear Administrator Leonhart,

The American Society for Pain Management Nursing (ASPMN) is an organization of more than 1700 professional nurses whose core purpose is to promote optimal pain management. ASPMN is dedicated to advancing and promoting optimal nursing care for people affected by pain. We take very seriously our obligation to inform our nursing colleagues, governmental agents, and the public on issues that concern pain management. ASPMN works independently and collaboratively to promote access to culturally appropriate pain care regardless of age, gender, or diagnosis, including (but not limited to) the access to prescription pain medications.

ASPMN is disturbed by the Drug Enforcement Administration's (DEA's) sudden withdrawal of the *Prescription Pain Medications: Frequently Asked Questions and Answers for Health Care Professionals and Law Enforcement Personnel (FAQ)*. We are compelled to respond to your request for comments because of the negative impact this action has already had on so many patients and their loved ones whom our members serve. We respectfully request that the DEA reverse its action and craft another statement, in collaboration with the scientific and medical communities, to stop the needless suffering of so many citizens inadvertently harmed by your action.

The withdrawal of the FAQ compels prescribers to replace the best scientific evidence with fear of reprisal as the basis of their decision making. The DEA's Interim Statement in the Federal Register has had a chilling effect on prescriber behavior among our physician and nurse practitioner colleagues. This statement undermines years of work with the professional community, including the landmark 2001 joint consensus statement, *Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act*. ASPMN was one of the twenty-one (21) organizations that proudly endorsed that document. This work established the need to balance two major health concerns affecting our country: (1) prescription drug abuse or diversion and (2) the widespread undertreatment of pain.

March 3, 2005

Dear Administrator Leonhart

Page 2

The collaborative work to create the FAQs was an essential first step in educating both prescribing clinicians and law enforcement agents about the need to provide legitimate, medically necessary pain management, along with an equally important vigilance to prevent prescription drug abuse and diversion. As partners in this endeavor, health professionals in the pain community have stepped up efforts to identify and halt diversion or abuse in their practice. The DEA has fallen short of its commitment to support this delicate "balance" by the content of the Interim Policy Statement in the Federal Register November 16, 2004, which, perhaps, unintentionally, suggests culpability for patients and prescribers until proven otherwise by DEA agents not trained in medical decision making.

For example, The Interim Policy Statement suggests that individualizing a dose of pain relievers to meet the patient's need is limited to what the DEA determines is an appropriate amount of medicine for all patients. For example, if a hospitalized cancer patient requiring 3 standard shots (30mg) of morphine per day to control his/her pain were to be sent home with an equivalent amount of oral medicine (e.g., 2 Percocet™ every 4 hours), the DEA would deem this as "condemned behavior" involving "inordinately large quantities of controlled substances." What if the prescriber had 10 or 20 or 2000 patients in their practice needing this type of pain management? The Federal Register Statement suggests that prescribers would have to withhold medicine from some patients to avoid regulatory scrutiny that will likely ensue. What we know from past research is that the very young, very old, women and ethnic minorities will suffer the most. This is in direct conflict with our national health priorities of 1) increasing the quality and length of healthy life and 2) eliminating health disparities.

ASPMN understands the reluctance of the DEA to "meet some arbitrary standard or threshold" to do its job; however, it seems as though the DEA has set some arbitrary standard, beyond which health professionals are not permitted to treat pain in accordance with evidence-based clinical guidelines or standards of care without "an investigation of a possible violation of the Controlled Substances Act." ASPMN members ask that the DEA consider the impact of sending an armed, uniformed officer into clinical settings to gain assurances that there are no violations. ASPMN members involved in these procedures report a significant fear among the patients, professionals, and staff, even when these intimidating tactics prove no wrong doing. The reports of a DEA raid investigating narcotic allegations are highly publicized, smearing the professional's reputation, which can not be undone by the meager or absent media reports of the Professional's innocence. These actions have certainly resulted in more prescribers joining the ranks of a growing majority, unwilling to jeopardize their careers by providing pain management in an environment of unreasonable DEA scrutiny that borders on slander.

The Interim Policy Statement prohibits the writing of several prescriptions on the same date with different fill dates. This represents a reversal of what was considered acceptable practice. This requirement is excessive for established patients with persistent or deteriorating conditions who are properly screened and monitored for months or years, demonstrating no evidence of aberrant drug-related behavior or an addiction disorder. This places an undo burden on clinical practices needing to create elaborate tracking systems to ensure that prescriptions are available at irregular timing intervals to prevent a painful and, perhaps, dangerous interruption of necessary medical care. Many offices cannot accommodate the increase in appointments that overtax their workload capacity, so accessibility is compromised to both established patients and new patients needing service. Where I practiced in Utah, every day I saw patients who needed to travel over 100 miles to the closest healthcare provider and/or pharmacy. The burden to make ill or disabled individuals travel that distance, perhaps more, is a burden overshadowed only by the fact that many payers are refusing to

March 3, 2005

Dear Administrator Leonhart

Page 3

reimburse for these excessive services for someone deemed “medically stable” adding to the toll taken on overtaxed families.

Reselling of controlled substances - ASPMN is concerned with the tone of comments regarding addiction and the treatment of known addicts. ASPMN adheres to the ethical principles of beneficence and justice obliging healthcare professionals to manage pain and to provide humane care to all patients, including those patients known or suspected to have an addictive disease. The Interim Policy Statement requires the physician to “avoid prescribing controlled substances with the knowledge that they will be used for a nonmedical purpose.” ASPMN acknowledges that the concurrent treatment of pain and addiction requires highly specialized skills, consultation, and monitoring. Occasionally, these specialists become aware of an instance where non-medicinal use of a prescribed medication occurs, and they modify the treatment strategy rather than abandoning the patient with complex and legitimate medical needs. It is unconscionable to disenfranchise an entire population from appropriate medical care whether for the treatment of pain or the disease of addiction.

In 2002, ASPMN published its position paper on *Pain Management for the Patient with an Addictive Disorder*. This document provides generic guidelines as well as specific recommendations for the patient in recovery, the patient who is actively using, and the patient on methadone maintenance. The DEA’s position diminishes the value of professional judgment and fails to recognize that appropriate management of addiction and chronic pain addresses the potential for increased drug abuse or relapse associated with unrelieved pain.

Although many nurses do not have prescriptive authority, the result of prescriber reluctance to use available, medically indicated safe and effective analgesic medicines leaves many in the position of providing care without the tools needed to do the job right. ASPMN finds it unacceptable that rather than a step taking advantage of medical progress and research over the past decades, we have reverted to practices that caused the Director of the National Institutes of Health to exclaim , “the way we treat pain borders on a national disgrace.”

ASPMN members respectfully request that the DEA consider their concerns and convey their desire to partner with law enforcement agencies, healthcare practitioners, and patient advocates to establish drug abuse prevention as an important societal goal in as much as it does not hinder legitimate access to care and medications for pain.

Sincerely,

Paul Arnstein

Paul Arnstein, PhD, RN, FNP-C
President, American Society for Pain Management Nursing