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October 6, 2003

U.S. Food and Drug Administration (FDA)
Subcommittee: Drug Safety and Risk Management (DsaRM)

Dear Committee Chair and Members:

The members of The American Society of Pain Management Nurses, an organization of 1,700 nurses dedicated to promoting and providing care of individuals with pain, recognize the challenges of balancing legitimate access to opioids for pain management and creating policy that effectively prevents diversion and abuse. Our organization stood with 21 other health care organizations and Administrator Asa Hutchinson of the Drug Enforcement Administration (DEA) on October 23, 2001 endorsing a joint statement in support of a critical balance between patient care and diversion prevention. ASPMN continues to support important legislation and regulation that preserves appropriate access to opioids for patients in pain. In Administrator Hutchinson's words, "We don't want to cause patients who have legitimate needs for these medications to be discouraged or afraid to use them. And we don't want to restrict doctors and pharmacists from providing these medications when appropriate."

Over the past decade many barriers to effective pain control have been addressed, but in spite of heroic efforts to improve pain management, clinician reluctance to prescribe strong opioids continues to be a barrier to effective pain management for many patients. Fear of regulatory scrutiny has been a documented link to under prescribing of opioids. We have an obligation to regulate the problem of diversion and abuse of opioids and a responsibility to do this without creating additional barriers to patients who have legitimate need to use these medications to control intractable pain. Scrutiny of modified-release opioids by the FDA must be balanced with the knowledge that this group of opioids is vital to effective management of chronic cancer and non-cancer pain. These patients are most likely to suffer at the hands of clinicians who are already fearful of regulatory scrutiny.

Diversion and abuse of modified-release opioids has received significant media attention. However, the media has failed to provide public education regarding the appropriate use of these medications and instead blames the illegal activities of those who divert and abuse these medications on the medication rather than on the person. We would call on the media to begin a campaign to educate the public regarding the appropriate use of these medications and the consequences of diversion and abuse.

Physician and pharmacist's lack of knowledge regarding the appropriate prescribing and monitoring of all opioids is a notable barrier to effective pain management. This becomes particularly problematic when there are those who would take advantage of legitimate channels to divert and abuse opioids. Medical schools must be encouraged to provide adequate education in their curriculum and state medical boards should require continuing medical education regarding pain management, appropriate use of opioids, and the monitoring that is essential when opioid

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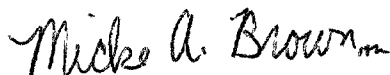
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treatment is ongoing. Increased awareness and knowledge by those who authorize or fill prescriptions will provide a beginning in the campaign to reduce diversion and abuse through legitimate channels while encouraging adequate knowledge so that appropriate prescribing is not compromised but rather supported by increased understanding.

Regulatory policies must balance the focus on diversion and abuse prevention with the needs of patients who suffer with significant pain. We appeal to the members of this committee to consider all opioids regardless of formulation or schedule status when writing new policy. Focusing regulatory scrutiny on specific opioids or opioid formulations has little chance of reducing illegal access to opioids through legitimate channels but instead poses a significant risk of creating yet another barrier to the appropriate prescribing of these medications for patients with legitimate needs. Regulations that require specific documentation of treatment plans, prescription monitoring, and appropriate use of electronic tools that facilitate communication regarding prescriptions should be unbiased and presented to physicians with adequate preparation so that it is possible to achieve the best outcome.

Risk management of opioids and improving the quality of pain management for patients who suffer moderate to severe pain cannot be accomplished in isolation. Efforts to improve one goal should include careful consideration of the other goal to truly be successful. Clearly, no one organization can foresee or provide all the answers. As members of The American Society of Pain Management Nurses, we are ready and willing to participate in developing policies that balance the need to prevent diversion and abuse with the need to minimize the barriers to accessing necessary treatments encountered by patients with legitimate pain problems.

Sincerely,

A handwritten signature in cursive script that reads "Micke A. Brown".

Micke A. Brown, BSN, RN
President