July 19, 2007

Washington State Agency Medical Directors Group
P.O. Box 44321
Olympia, Washington 98504

Re: **The Washington State Agency Medical Directors Group (AMDG) published guidelines on Opioid Dosing for Chronic Non-cancer Pain**

Dear Sirs,

The American Pain Society is a multidisciplinary community that brings together a diverse group of scientists, clinicians, and other professionals to increase the knowledge of pain and transform public policy and clinical practice to reduce pain-related suffering. Our overall aim is similar to yours – provide safe and effective pain relief using scientific, evidence-based knowledge. As such, we read with concern the recently published guidelines on Opioid Dosing for Chronic Non-Cancer Pain and would like to offer the following thoughts:

- We know of no scientific evidence that the Washington State Agency of Medical Directors Group's Opioid Dosing Guidelines will improve the safety, and diminish harm of patients within the state sponsored healthcare programs who are receiving opioids for chronic non-malignant pain. We are also extremely concerned with the recent rise in deaths attributed to opioid misuse, however, we feel that it is imperative that the latest and most sound scientific evidence be used in the management of any patient who suffers from pain from any etiology. It is our ultimate goal as a society, to ensure that the fair and equitable treatment of pain is available to any patient who suffers from pain.

- We are worried that the recent emphasis on improving pain control by the American Pain Society has been misconstrued by the AMDG and others to mean that opioids must be "aggressively" escalated to achieve this goal. It is important to clarify with the AMDG and others that opioids and other non-opioid analgesics should not be withheld due to unfounded fear and biases. Instead, they should be used in accordance with the latest scientific evidence and clinical practice guidelines by adequately trained healthcare professionals.

- We are troubled that the guidelines are primarily based on one retrospective study (Franklin et al, 2005). Furthermore, we believe these data to be flawed. This study in workers compensation patients fails to provide documentation of the dosage of opioids taken by the 44 patients whose deaths were determined to be "prescription–opioid related deaths" rated as definite (32) or probable or possible (12). It is not clear whether these patients were taking a Schedule II opioid. Additionally, the authors were not able to report the relationship between death rates and temporal exposure to opioids. Is the increase in deaths truly a function of increased exposure to opioids? Moreover, the authors found that, like the general trend in the US, the number of Schedule II opioid prescriptions in Washington State increased from 1996 to 2002 (by 2.5 fold in Washington State). Yet, in spite of the steady increase in Schedule II opioids from 1996 to 2002, the number of opioid related deaths (definite, probable, and possible) peaked in 2000 at 12 and had declined to 8 by 2002.

- We are hopeful that the guidelines will meet their intended outcome "to aid in reducing death and morbidity related to opioid dosing for treatment of chronic non-cancer pain." But we are also concerned with the precedent that the guidelines present to other states considering similar legislation without knowing the full impact, if any, on the patients who experience chronic pain in the state of Washington.

- We are troubled that the current guidelines potentially add unnecessary restrictions and additional barriers to patients who experience pain, and potentially discriminate against those patients without a cancer diagnosis and further worsen medical access for those who do not meet the current criteria. We believe that the guidelines may introduce unintended consequences for persons who develop chronic pain as a consequence of the treatment for cancer.

- We are disturbed with the defined criteria that identify patients who exhibit "drug-seeking behavior" since there are no diagnostic behavioral criteria or accepted medical definition. We are concerned that the premature identification of a patient as a "drug-seeker" may incorrectly identify a pseudoaddict, or introduce an unintended burden to other patients further diminishing the availability of adequate treatment of their pain.

- We don't even know whether there are enough pain specialists within the State of Washington to meet the demand of all the patients that exceed the 120mg/day of morphine equivalents, particularly in rural areas.
  We respectfully appreciate your efforts to regulate opioid use in your state but feel that there is still much more work to do to make these guidelines practical and appropriate. We offer our society's expertise to collaborate with AMDG to generate scientifically sound and measurable outcomes related to these guidelines or to provide assistance in future or present development of treatment algorithms for pain. It is imperative for all interested parties to find an optimal balance between harm from opioids and optimal pain control.

Sincerely,

Judith A. Paice PhD RN
President