February 12, 2002

The Honorable Edward Kennedy
Chairman
The Honorable Judd Gregg
Ranking Member
Senate Health, Education, Labor, and Pensions Committee
United States Senate
Washington, DC 20510

Dear Chairman Kennedy and Ranking Member Gregg:

On behalf of the more than 29,000 nurses and other health professionals of the Oncology Nursing Society (ONS), we are writing to thank and commend you for holding a hearing on issues relating to Oxycontin® and recent reports of its abuse. ONS, the largest professional oncology group in the United States, exists to promote excellence in oncology nursing, teaching, research, administration, education in the field of oncology, and the provision of quality care to individuals affected by cancer. As part of its mission, the Society stands ready to work with policymakers at the local, state, and federal levels to advance policies that will reduce and prevent suffering from cancer, including initiatives that improve pain and symptom management and enhance quality-of-life. We appreciate the opportunity to share with you our views - and submit this correspondence to be included in the hearing record - on the importance of appropriate access to and use of opiates - such as Oxycontin® - in cancer related pain and symptom management.

Under-treated Pain - A Major Public Health Problem

It is perhaps one of the more tragic realities in health care today that, despite the existence of many drugs and techniques for treating pain, countless individuals continue to suffer needlessly from unrelieved pain. Pain is a major health problem in the United States, especially the kind of pain that often is experienced by individuals with cancer. The treatment and management of pain and accompanying symptoms such as fear, anxiety, depression, weakness, nausea, and vomiting need to be improved significantly. When pain is severe, it

interferes with activities and quality-of-life; diminishing physical, psychological, and interpersonal well-being. ONS believes that the inadequate treatment of pain is a significant public health problem in the United States and requires the necessary public health response.

Although efforts at educating health care professionals and the public have helped us to make considerable progress in improving the adequate treatment of pain, still less than half of patients with cancer receive adequate relief of their pain. Unfortunately, approximately one in four patients with cancer die with unrelieved pain This is in spite of the fact that medications and other therapies currently exist to relieve almost all of cancer pain. Much of the failure to relieve cancer-pain stems from patient, provider, and family misconceptions and fears. Moreover, recent controversies and negative media attention regarding the use of opiates have begun to erode much of the progress that had been achieved in this arena. Adequate pain control further is complicated by regulatory agencies that scrutinize professional licensure and restrictively regulate controlled substances - practices that tend to frustrate legitimate use rather than stem diversion. It is, indeed, an unfortunate reality that the class of drugs that has the potential to alleviate pain and suffering also has the potential to be abused. However, while it is essential to strike a critical and delicate balance between legitimate access and efforts to prevent diversion and abuse, it is essential to note that there is abundant evidence that the vast majority of those who use these drugs for their legitimate and intended purpose, do not go on to abuse them.

Much of the progress that has been made over the past two decades in increasing understanding and awareness of the benefits of effective pain management has been made in the area of oncology. To address issues related to the under-treatment of cancer pain, position papers, educational materials, guidelines, and standards have been adopted by various organizations - including ONS (see attachments). In addition, surgery, radiation, and chemotherapy may be used to control the pain by shrinking the tumor. However, drugs such as non-opioids, opioids, and adjuvant medications are the mainstay of pain treatment.

Greater emphasis on quality-of-life for individuals at end-of-life and the growth of hospice care in this country also have done much to validate the role of opiates in treating pain

and suffering. Additionally, concurrent advances in the treatment of cancer have yielded a growing population of patients who are living longer with cancer as well as an increased number of people who are cured and therefore transition to cancer "survivorship." Many of those patients who live long-term continue to experience pain that may be related to their treatment rather than the malignancy itself. These patients often suffer moderate to severe pain on a daily basis which compromises their ability to function in various life activities. Therefore, this cohort has more in common with the non-malignant pain patient than the patient who has pain associated with advancing disease. For example, pain may be due to nerve injury or scar tissue formation from cancer-related surgical intervention.

Despite significant breakthroughs in the treatment, early detection, and prevention of cancer, two-thirds of new cancer cases strike people over the age of 65 and the number of new cancer cases diagnosed among the elderly is projected to more than double by 2030 as the Baby Boom generation ages. As cancer risk increases with age, so does the risk and incidence of other chronic conditions. Therefore, many who develop cancer also suffer from other co-morbidities and underlying painful conditions associated with their other health problems such as arthritis, diabetes, or prior trauma. Clinical experience in this population has suggested that symptomatic treatment of pain with opiates is effective regardless of the underlying cause of the pain, and that treatment decisions should be based on the nature of the pain, the pain intensity, and response to treatment rather than whether the cause of the pain has a malignant or non-malignant origin.

Children also have benefited from the advances in pain treatment. As we have become better able to assess pain in children, even at very young ages, we have seen the benefit to quality-of-life afforded by effective control of pain. Yet, recent studies alert us to the fact that dying children are not being managed effectively regarding pain, causing needless suffering for them and their parents at this critical and distressing time.

Under-managed pain often results in emotional and economic consequences both of which have long term costs to affected individuals and their families. Therefore, it is essential that improved quality-of-life through expert pain control be available to all who experience

pain, not just a select class of patients with specific diagnosis. We must do more to ensure that appropriate pain management is the standard of care - for the young as well as the elderly, and for those with chronic illness or at end-of-life.

Opioid Treatment Essential to Managing Cancer-related Pain

For years, morphine has been the standard opioid of comparison to treat severe pain in cancer patients. However, as knowledge about pain physiology and pharmacology translates into better analgesics or new formulations of opioids with fewer side effects, morphine has not remained the drug of choice. Morphine has several active metabolites including morphine 6-glucuronide and morphine 3-glucuronide that may accumulate in patients with renal disease, renal dysfunction, or elderly persons because of decreased clearance and prolonged elimination half-life. When this occurs, patients taking morphine may become confused, disoriented, sedated, and may experience other side effects. Because of these problems related to morphine's active metabolites, the trend has been to use semisynthetic opioids such as oxycodone, fentanyl, and hydromorphone.

Cancer patients typically have two types of pain – continuous, persistent pain that is always present and intermittent or breakthrough pain that occurs with activity. Patients, therefore, need to be treated with continuous release opioids (usually dosed twice a day) for the persistent pain and short acting opioids (usually dosed every two to four hours) for the breakthrough pain. At present the only continuous release opioids that are available are morphine (MS Contin®, Oramorph®, Kadian®), oxycodone (Oxycontin®), and fentanyl (Duragesic patch® typically dosed every 72 hours). Currently, there is no continuous release hydromorphone product available. If continuous release oxycodone (Oxycontin®) were to be regulated strictly, this could pose a major problem not only for people with cancer but a multitude of patients with chronic nonmalignant pain who are enjoying an improved quality-of-life because of Oxycontin®. Some cancer patients cannot tolerate morphine because of side effects of nausea and vomiting while others need to take high doses of continuous release oxycodone because they are not able to use the fentanyl patch as they would need multiple patches to equal the Oxycontin® dose they are taking. With the availability of controlled

release oxycodone, cancer patients are able to have access to another analgesic for relief of persistent pain. If access to opioids - such as Oxycontin® - is to be restricted severely, many patients would not be able to maintain a decent quality-of-life.

Diversion Control, Abuse Prevention, and Legitimate Access - A Delicate But Necessary Policy Balance

Clearly, this class of drugs needs to be regulated in an appropriate fashion so as to prevent and reduce diversion and abuse. However, in these important efforts, we must not increase the burden to patients or the health care professionals who are administering their pain-related care. Regulations that limit reliance on professional clinical judgment and unduly restrict access encumber the provision and delivery of appropriate pain management for patients with legitimate needs.

ONS maintains that our nation's policies related to diversion control and abuse prevention should not target one drug over another. As all of these drugs can be misused, the Society asserts that regulations and actions must focus on individual behavior and enforcement of the law, not on reducing access to a particular therapeutic agent. Our organization believes that all people with legitimate need must be assured access to the medication and therapies that they and their health care providers deem most appropriate. While we do not take positions advocating one particular drug over another, we feel strongly that drugs approved by the Food and Drug Administration (FDA) for pain and symptom management should be accessible to patients in need. However, we recognize and appreciate that with the potential for abuse, our nation must develop and implement appropriate yet reasonable practices and regulations to ensure that these drugs do not fall into the wrong hands and are not abused.

The percentage of the population who take prescription drugs for non-medical purposes has remained stable for the last decade at 1-1.5 percent as has the percentage of the population with an illicit drug problem (6-7 percent). This suggests that while periodic hotspots develop around a particular drug in certain communities, overall our nation's policies are working to minimize drug abuse. To that end, a study of opioid use and abuse recently published in the Journal of the American Medical Association concluded that the increase in medical use of

opioid analgesics does not contribute to the increase in abuse.[1] However, we unfortunately have always had to be aware that an individual's request for a certain drug could be based in real need/response but could also be based on its street value. Yet, as noted above, we continue to see significant numbers of people with cancer dying in pain. This indicates that while our policies work to stem the tide of abuse they may be standing in the way of legitimate and necessary quality care.

ONS Recommendations

As part of our nation's ongoing effort to minimize diversion and abuse, nurses monitor the effects of controlled substances - including positive and negative effects, screen for drug use and abuse in daily practice and make referrals when appropriate. Oncology nurses have been leaders in providing pain education and our organization provides education to our members through our journals, at conferences, and at special events. Nurses are experts in developing patient educational materials and work to teach patients how to manage their opioids, including safety issues. Moreover, nurses collaborate in teaching children in their community about drug abuse.

To augment and enhance these efforts, we feel strongly about the need for improved educational efforts that include how to stop drug diversion, how to keep records, and how to document proper assessment and prescription distribution. Specifically, health care professionals need access to education and training regarding pain control, especially with respect to the safe and appropriate use of opiates. Education and support are essential for health care professionals who prescribe and monitor patients using opiates in order to counter the intimidation that is often felt in the current climate where so much attention is focused on stemming diversion and abuse. Such education must include law enforcement, physicians, nurses, and pharmacists and should involve the national organizations representing these professionals (e.g. National Association of State Controlled Substance Authorities and National Association of Drug Diversion Investigators). These educational initiatives must focus equally on legitimate pain management and prevention of diversion and abuse. Unfortunately, many

[1] Data from 1990-96), Joransen DE, Ryan KM, Gilson AM, Dahl JL. Trends in medical use and abuse of

of the individuals and entities currently engaged in efforts relating to prescription drug abuse do not have a comprehensive understanding or perspective of the nature of pain and the associated therapies.

In addition to education, we recognize that some changes to our current system might be necessary to thwart diversion and abuse. To that end, one possible solution would be to consider tamper proof prescriptions that cannot be photocopied. In addition, a national monitoring system could be developed that would allow the DEA to have better information to do its job. In an effort to identify what is needed, the government could conduct a study of prescription monitoring that empowers law enforcement and healthcare providers more comprehensive information. Currently, the DEA can look at DAWN information but that is voluntary reporting from emergency rooms and at best, provides a clouded picture. We understand from our members who practice in pain management groups that healthcare providers would be interested knowing in if the individual they are treating is receiving scripts elsewhere. ONS stands ready to work with Congress, DEA, and other stakeholders to engage in such an effort to identify, capture, and disseminate more meaningful information about the use and potential abuse of prescription main medications. To complement this study, we urge additional research on the on prevalence and root causes of prescription drug abuse.

We urge the Committee to use the current situation with Oxycontin as an opportunity to look at the general issues of pain and symptom management and prescription-drug abuse, addiction, and treatment. Our national health system offers little in terms of treatment and ONS advocates funding additional research in this area. For both pain management and addiction and treatment, it is important to note that the data are very poor in this area and practices are not standardized. For example, medical examiners are not using the same screening methods for drugs and we have little quality data from medical examiners. Moreover, in some areas the medical examiner changes yearly which precludes consistency in policy and practice. We urge the Committee to examine the current reporting system and consider possible improvements.

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opioid analgesics. JAMA 2000;283(13):1710-1714.

ONS maintains that steps can be taken to prevent diversion and abuse while promoting access to opiates for legitimate pain relief. To that end, ONS recommends that the federal government should:

1. Establish and maintain an ongoing dialogue between the Food and Drug Administration (FDA), the Drug Enforcement Agency (DEA), and health care professionals to encourage cooperation and mutual understanding in an effort to ensure a balanced and rational approach to effective symptom management and minimization of illicit drug use;

2. Work with health care professionals to develop guidelines for practice that will assure access to opiates based on sound clinical judgment and patient need, while increasing early recognition of problem behaviors;

3. Develop educational materials for patients and family members that will reassure them of the legitimacy of opiates in treating pain while giving them guidelines for safe use and the prevention of diversion or abuse;

4. Allocate resources to educate health professionals about the appropriate use of opiates and associated pain management techniques, both pharmacological and non-pharmacological;

5. Support projects aimed at identifying and eliminating system level obstacles that preclude effective pain management in acute pain, cancer pain, and chronic pain; and

6. Assure that federal publications delineate clearly between substance abuse and legitimate pain management in acute pain, cancer pain, and chronic pain as the evidence that addiction is very rare in patients who have pain should be acknowledged more widely.

On behalf of ONS and our members who are involved in the provision of cancer-related pain and symptom management, we thank for your consideration of our views on this important matter. ONS affirms its commitment to promoting the relief of cancer related pain and suffering and urges your Committee to consider first and foremost, the needs of those who

suffer needlessly from unrelieved pain and to take steps to assure their continued access to the pain relief they need. We urge your attention to the broader issues of pain management and barriers to quality pain and symptom management as opposed to focusing solely on a particular therapeutic agent. Without a comprehensive evaluation of the current system of pain management, the potential unintended adverse repercussions of changing federal regulatory policy related to one drug could lead to fear and diminished access to care among those with legitimate needs.

Please know that we are available to offer our support and expertise to your Committee, Congress, the FDA, and the DEA to achieve our mutual goal of preventing diversion and abuse of pain therapies while also ensuring that patients with legitimate pain continue to have access to the quality, appropriate, and legitimate relief they need and deserve.

Sincerely,

Paula T Rieger

Paula Trahan Rieger, RN, MSN, AOCN, CS, FAAN
President

Pearl Moore

Pearl Moore, RN, MN, FAAN
Chief Executive Officer

Attachments:
Oncology Nursing Society Position - Cancer Pain Management
Oncology Nursing Society Position - Quality Cancer Care