U. S. Department of Justice
Drug Enforcement Administration

Washington, D.C. 20537

NOV 0 7 2001

Ms. Ellen L. Stovall
Cancer Leadership Council
1900 K Street, N.W., Suite 750
Washington, D.C. 20006

Dear Ms. Stovall:

This is in response to your correspondence dated September 19, 2001, which included additional correspondence regarding the possibility that policies will be implemented that will restrict the availability of opioids used to treat pain. In your letter, you point out that any such restriction would have a detrimental effect on the quality of life for patients suffering from cancer pain as well as other chronic pain syndromes.

I would like to assure you that the Drug Enforcement Administration (DEA) has no plans to restrict legitimate use of opioids nor are attempts being made to prevent practitioners acting in the usual course of their medical practice from prescribing medications for patients with legitimate medical needs. In seeking ways to address the abuse and diversion problems with potent opioids, DEA has examined numerous alternatives. When considering alternatives and seeking solutions to the abuse and diversion of opioids, we are in agreement with pain management specialists that a critical aspect of the problem's solution is ensuring that knowledgeable and appropriately trained practitioners are the professionals who prescribe these medications. The DEA does not seek to limit the access of any patient with legitimate medical need to opioids, nor do we claim any responsibility for regulating medical practice. In fact, federal laws and regulations do not attempt to define "legitimate medical need" nor do they set standards as to what constitutes "the usual course of professional practice." The DEA relies upon the medical community to make these determinations.

In keeping with this reliance on standards set by medical professionals for medical professionals, DEA has been a strong supporter of the Federation of State Medical Boards' "Model Guidelines for the Use of Controlled Substances in Pain Management." As you point out, a contributing factor to the undertreatment of pain is the misunderstanding of the appropriate use of opioids by clinicians, regulators, and the public. These guidelines are invaluable in overcoming this misunderstanding.

In the four years prior to the introduction of OxyContin® in 1996, the number of emergency department reports involving oxycodone, the active ingredient in OxyContin, remained relatively stable. By 1999, the number of reports doubled and has been increasing steadily since. Similarly, DEA has received an increased number of coroner reports citing OxyContin® as a cause of death. The dangers posed by OxyContin® abuse are also evidenced by reports received from narcotic treatment programs in states like West Virginia, Kentucky, Pennsylvania and Virginia that indicate 50 to 90 percent of newly admitted patients stated OxyContin® was their primary drug of abuse. Officials in these states, who describe this trend as an epidemic, report that entire towns have suffered from the effects of illicit OxyContin® trafficking and abuse.

The DEA has been working with the healthcare community, pharmaceutical industry and other government agencies in order to address this growing threat to public health and safety. The DEA has a well-established relationship with experts in a variety of medical specialties, including both pain and addiction specialists, and we have enlisted their expertise in devising strategies in order to ensure that potent opioids are appropriately prescribed. There is considerable consensus within the pain management community that medical education is not always sufficient in providing practitioners with the training necessary to effectively manage chronic pain. These experts emphasize that Schedule II opioids are best used as the treatment of last resort for chronic pain; and that when they are used, they should be part of a multi-disciplinary approach to include physical and psychological therapy.

The DEA agrees with you that improving the knowledge of healthcare professionals and patients regarding the use of opioids is vital in assuring adequate treatment of pain as well as preventing the abuse and diversion of these products. Physicians frequently face the dilemma of distinguishing between patients in legitimate need and individuals engaged in drug-seeking behavior. It is feared that in the well-intentioned push to ensure adequate treatment of pain by some less experienced practitioners, the terms 'pain treatment' and 'opioid treatment' have become synonymous. It is only through a cooperative effort between DEA and the medical community that an adequate solution to this dilemma will be found. As part of this cooperative effort, I have met with representatives of pain management groups and together we are working to find the balanced approach to the regulation of pain medications that you recommend in your letter.

I trust this information has helped to allay any concerns you have regarding DEA's commitment to ensuring that patients with legitimate medical needs have adequate access to opioid analgesics while we strive to protect the public from the consequence of the abuse of these products.

In recognition of this commitment, the Board of Directors of the American Pain Society adopted a resolution commending DEA for its efforts to promote adequate pain management, a copy of which is enclosed for your review.

Sincerely,

Asa Hutchinson
Administrator

Enclosure

Resolution Recognizing Efforts by the Drug Enforcement Administration to Improve Pain Management

Whereas, Studies and clinical experience demonstrate that the use of opioid analgesics is recommended for the treatment of patients with pain due to cancer, as well as for selected patients with pain due to chronic non-cancer conditions;

Whereas, Studies and clinical experience demonstrate that health-care professionals are concerned about being investigated or disciplined by a regulatory agency due to the use of opioid analgesics to treat pain, thus contributing to inadequate pain management;

Whereas, The U.S. Drug Enforcement Administration has participated in various national pain conferences to clarify the role of law enforcement and to address health-care professionals' concerns about regulatory scrutiny when prescribing, administering or dispensing opioid analgesics;

Whereas, The U.S. Drug Enforcement Administration has participated in a collaborative project to improve communication between representatives of prescription monitoring and the American Pain Society;

Therefore, Be it resolved that the American Pain Society commends the efforts of the U.S. Drug Enforcement Administration to promote adequate pain management.

Adopted by the Board of Directors of the American Pain Society, on April 18, 2001

Michael A. Ashburn
President