

## **Anesthesiology and Critical Care Medicine**

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August 13, 2001

Kimberly Topper  
Food and Drug Administration, CDER  
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5600 Fishers Lane  
Rockville, Maryland 20857

Dear Ms. Topper:

I would like to thank you for the opportunity to enter into what I trust will be a productive dialogue on the appropriateness of prescribing opioids to treat chronic pain. While we recognize that by improving the availability of opioids to patients who need them, we risk increasing access to members of the general public who may abuse these drugs, we must be very careful not to penalize our most vulnerable patients – those who suffer pain from chronic conditions.

Thus, while we consider how best to address the recent and highly publicized crisis caused by diversion and abuse of a prescription medication, it is important that we recognize the vital position opioids occupy in the management of acute and chronic painful disorders. In fact, the opioid class of medication provides the most effective treatment for moderate to severe pain and could not be abandoned without grave ramifications for countless individual patients and for society as a whole. Instead of denying legitimate access to opioids, therefore, we must seek strategies that will eliminate diversion.

Over the past decade, we have made great progress in our understanding that opioids occupy a legitimate role in the management of pain. In the early 1990's, many members of state medical examination boards believed that it was inappropriate to prescribe opioids for nonmalignant pain. These boards went so far as to countenance the investigation of any physician who took such action. This policy instilled an undercurrent of fear into the hearts of many physicians, decreasing their willingness to prescribe opioids and leading to poor quality pain management throughout the country.

Fortunately, these inaccurate and restrictive attitudes changed as a wealth of information

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accrued on the efficacy of opioids, the low incidence of addiction, and their manageable side effects. Today, literally hundreds of thousands of patients have been monitored while receiving opioids, and we now know that we can improve the quality of pain care delivered to the millions of Americans currently suffering or destined to suffer from acute and chronic pain only if opioids remain part of the clinical regimen.

Numerous federal and scientific societies have evaluated the appropriateness of administering opioids as part of clinical practice. The Agency for Healthcare Policy and Research has published two guidelines on the management of cancer and acute pain, both of which incorporate the administration of opioids. The Joint Commission on Healthcare Organizations has mandated the appropriate management of pain and the inclusion of pain control assurances in the Patients' Bill of Rights. This cannot be accomplished if opioids are withheld from the paradigm of good clinical practice. The American Pain Society and the Academy of Pain Medicine, two of the most important scientific and clinical pain societies in America, have issued a joint position statement indicating that the prescription of opioids in the management of pain is appropriate in selected cases.

Most physicians recognize, however, that prescribing opioids is not risk-free. As with many drugs, these therapies can be misused. There remains a concern about addiction and, as the current crisis underscores, about the diversion of controlled substances. There may also be occasions in which opioids are prescribed in lieu of more appropriate conservative care or of a permanent option. We must maintain constant vigilance, therefore, to assure that we are offering patients the highest possible quality care without otherwise jeopardizing the health of Americans.

Although addiction is an ongoing concern, the fact is that it occurs rarely. While estimates vary, true addiction is thought to occur in 3-6% of the adult population. There is no reason to suspect that the prevalence of addiction is any higher in the pain clinic population or in the general medical community (where opioids are administered in a controlled setting and monitored carefully).

In addition, the development of long-acting opioids is at least partially responsible for the improved safety of these formulations – because they are not associated with immediate pain relief or induction of a “high,” they are safer for legitimate patient use than short-acting, “less potent” medications. Indeed, the instances of abuse highlighted in the media require breaking this safety barrier by converting the long-acting opioid into an immediate-release preparation through chewing or otherwise destroying the sustained matrix.

As we move forward, we need to maintain a sense of balance. We need to reassure physicians that it is legally safe to prescribe opioids in the legitimate practice of medicine, even as we investigate any who may be engaged in criminal activity. We need to assure our patients that they will continue to have access to the only medications that can help them manage their intractable pain, even as we assure ourselves that criminals are unable to divert prescribed substances for illicit use. We need to instruct our patients that selling their medications is a criminal act, with criminal penalties.

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There is an old saying that illustrates the futility of closing a barn door after the horse has escaped. It is equally senseless to shoot the horse just because it escaped. I would be happy to contribute to the development of a strategy that ensures the continuation of the appropriate administration of opioids while incorporating ways to prevent their illicit diversion and abuse.

Sincerely,

A handwritten signature in black ink, appearing to read 'P. Staats', with a large, stylized flourish at the end.

Peter S. Staats, M.D.  
*Director, Division of Pain Medicine*  
*President, Southern Pain Society*  
*President Elect, American Neuromodulation*  
*Society*  
*Secretary, National Pain Foundation*

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