



September 17, 2001

Kimberly Topper
Food and Drug Administration, CDER
Advisors and Consultants Staff, HFD-21
5600 Fishers Lane
Rockville, MD 20857

Dear Ms. Topper,

Attached you will find comments submitted by the American Cancer Society for the Anesthetic and Life Support Drugs Advisory Committee meeting to be held on September 13 and 14, 2001.

If you have any questions regarding this document, please contact me at (202) 661-5720.

Thank you for your assistance in this matter.

Sincerely,

A handwritten signature in cursive script that reads "Ted Billings".

Ted Billings
Manager, Federal Government Relations

STATEMENT OF THE AMERICAN CANCER SOCIETY

Meeting on Medical Use of Opioid Analgesics

UNITED STATES FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
ANESTHETIC AND LIFE SUPPORT DRUGS ADVISORY COMMITTEE

Contact

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Statement of the American Cancer Society

Anesthetic and Life Support Drugs Advisory Committee

September 14, 2001

The American Cancer Society is the nationwide community-based voluntary health organization dedicated to eliminating cancer as a major health problem by preventing cancer, saving lives and diminishing suffering from cancer through research, education, advocacy and service. Nationwide, more than 28 million volunteers and supporters, including cancer survivors, researchers, healthcare providers and educators, contribute their time and resources to help advance the Society's goals. The American Cancer Society has set ambitious goals for the year 2015 to reduce the number of people dying from and being diagnosed with cancer and to significantly improve the quality of life for all cancer patients, survivors, and their families.

PAIN IS A MAJOR HEALTH PROBLEM

Pain is a major health problem in the United States, especially the kind of pain that is often experienced by individuals with cancer. A diagnosis of cancer can immediately throw a person into a cycle of pain, test tubes, needles and debilitating limitations. When pain is severe, it can lead to fear, fatigue, anxiety, and depression. It can interfere with day-to-day activities and diminish a person's physical, psychological, and interpersonal well-being. Our nation's current treatment and management practices for pain and its accompanying symptoms must be improved significantly.

Today's science is strong enough that the majority of individuals with cancer pain can indeed find relief by using current drugs and other types of pain relief techniques. Cancer patients need not suffer from cancer pain. In fact, when cancer pain is controlled, patients and their doctors can dedicate more energy to fighting the cancer. For those individuals who remain in pain despite the application of standard treatment regimens, additional consultation with acknowledged experts in the field should be sought.

The American Cancer Society believes that the inadequate treatment of pain is a significant public health problem in the United States.

- Approximately 50 to 70 percent of cancer patients experience uncontrolled pain at some point during their illness, depending on the stage of the disease.

- Research indicates that more than half of patients with cancer do not get adequate relief of their pain in spite of the fact that medications and other therapies currently exist to relieve almost all of cancer pain.
- Pain is one of the most common and most feared symptoms of cancer.
- Under-treatment of pain has significant adverse effects on quality of life and has been associated with serious patient despair and depression.

It is the goal of the American Cancer Society to increase awareness, and promote effective pain management for persons with cancer from the time of diagnosis and throughout the balance of life.

While numerous treatment options are available for controlling cancer pain, many barriers still exist for patients and their health professional partners. One of the most serious of these barriers lies in the myths surrounding pharmaceuticals, such as opioids – a class of federally controlled substances, such as morphine and oxycodone. Such myths include patients' fear of addiction, fear of building tolerance to pain medication and fear that pain medication will make the patient lose mental or physical control. The fear of regulatory scrutiny also inhibits provider treatment of cancer patients' pain—particularly in cases involving medications such as opioids that have been known to draw the attention of drug enforcement officials. While nothing in federal law directly prevents the appropriate use of opioids for pain management, fear of controlled substances and the manner in which the laws that govern them are enforced contribute to inadequate treatment of cancer pain. A result of this fear is that cancer pain may remain under-treated.

Public and provider education is greatly needed to correct these widely-held and false beliefs. Cancer patients should know, as we know, that good cancer pain management does not result in addiction. Physicians and other medical practitioners should not fear that they would be prosecuted for appropriately treating their patients' cancer pain.

The American Cancer Society recognizes there is an important need to improve the quality and increase the use of adequate cancer pain treatment. The Society also recognizes and supports the strong societal interest in assuring the appropriate use of controlled substances. We realize that the diversion of opioids does occur and should be addressed. However, we are greatly concerned that attention to the misuse of controlled substances has overshadowed and impeded attempts to manage pain. Currently, our nation has not found a proper balance between these two issues and the cost has been at the expense of those who need their pain controlled.

REGULATORY BARRIERS TO QUALITY CANCER PAIN MANAGEMENT

The American Cancer Society believes that our nation must strive to protect and encourage legitimate pain treatment, while addressing the real dangers of prescription drug diversion and abuse. The Society strongly supports a balanced policy toward the regulation of pain medications that are also controlled substances. The Society supports appropriate law enforcement actions to ensure that controlled substances, including pain medications, are used only in the course of legitimate medical practice, but the Society opposes efforts to limit the distribution or availability of pain medication to the patients who need them. While we agree that opioid medications should be kept out of illegal or improper hands, the Society opposes law enforcement activities that have unintended, but harmful effects on people with pain. The Society opposes activities that threaten to roll back hard-won progress that has expanded the use of opioids, as a viable option for treating pain. Those with legitimate needs should not be made to suffer due to the actions of those who violate the law.

The American Cancer Society strongly supports the primacy of clinical decision-making between patients and health care providers and opposes any efforts that might have a chilling effect on health care providers' willingness and ability to provide pain medication and pain management when treating patients with cancer and other serious or life-threatening illness.

CONCLUSION

In conclusion, the American Cancer Society believes that the inadequate treatment of pain is a serious public health problem. Opioids provide effective treatment for many patients with pain, especially cancer patients. We must work together to ensure that those who need treatment for pain have not only safe and effective treatment, but also have adequate access to that treatment.