



American Alliance of Cancer Pain Initiatives

October 10, 2003

Anesthetic and Life Support Drugs Advisory Committee
Food and Drug Administration
Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

To Whom It May Concern:

We are writing in response to the FDA's Anesthetic and Life Support Drugs Advisory Committee hearings, held on September 9 and 10, 2003. We have serious concerns about the possible deleterious impact of some of the proposals discussed at this meeting. The American Alliance of Cancer Pain Initiatives (AACPI) is a national organization composed of primarily state-based grass-roots initiatives dedicated to promoting the optimal relief of pain for people with cancer. We strongly support the principle of balance in drug control policies affecting pain management. Balance represents a dual obligation of governments to establish controls to prevent abuse and diversion of narcotic drugs, while at the same time ensuring their medical availability. Therefore, in evaluating public policy related to these medications, we seek solutions that do not unduly restrict access to these medications for those who need them while simultaneously making access more difficult for those abusing them. We believe that some of the suggestions made at the hearing are unbalanced and will deny many patients access to appropriate medical care.

Our first concern is with the proposal to limit use of controlled release opioids (CROs) to patients with severe pain. Defining "severe" pain is a highly individualized, subjective matter. It is not appropriate for healthcare practitioners or regulators to define, on a predetermined basis, what constitutes severe pain for any individual patient. Any such definition would most likely be based on the degree of functional impairment associated with the patient's pain experience. While it is true that research has linked increasing levels of pain with increasing degrees of functional impairment, there remains great individual variability, such that one person reporting a given pain intensity may have much more or less functional impairment than another person reporting the same level of pain. Secondly, CRO analgesics are safe and effective when used as recommended by patients with moderate, as well as severe, pain. There are no scientific data to support the notion that patients with moderate pain are any more prone to abusing opioid analgesics than patients with severe pain.

Our second concern lies in the proposal to limit CRO prescribing to pain specialists. Individuals in many medical specialties treat pain. Most of these physicians use opioid analgesics with great care. It is these individuals, not pain specialists, who manage most of the pain for most of the patients in this country. In many areas, access to pain specialists is extremely limited, and a large proportion of such physicians practice primarily interventional pain management, with minimal expertise in the use of opioids. Given that some patients achieve maximal pain relief only after trials of multiple medications, requiring these patients to seek out the few pain specialists would create an unrealistic and onerous burden and result in further undertreatment of pain.

Promoting Cancer Pain Relief Nationwide

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We support requiring extensive risk management plans for new opioid analgesics. Recent experience with the abuse of CROs is unprecedented and completely unexpected. Until we better understand the factors that have produced this experience, it is incumbent upon pharmaceutical manufacturers and regulatory agencies to undertake extensive study of methods to prevent the abuse and diversion of these medications. We support an extensive risk management program, lasting for years, rather than months. The nature of such a program requires careful consideration so that, referencing the principle of balance outlined above, it does not unduly restrict access to these medications by people who need them. Therefore, the AACPI believes that risk management plans should emphasize provider and patient education about the risks and benefits of CROs. Such an approach should provide all parties involved with accurate information that allows them to make informed decisions about the appropriate use of these medications.

Sincerely

Robert Twillman, PhD
Chair, Advisory Board
American Alliance of Cancer Pain Initiatives