



National Hospice and Palliative Care
Organization



April 10, 2009

Dr. Janet Woodcock
Director, Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
Building 51, 6th Floor
Silver Spring, Maryland 20993

Re: The Availability of Adequate Pain Management Options for Hospice Patients

Dear Dr. Woodcock:

The Hospice and Palliative Care Coalition (“Coalition”) appreciates the opportunity to work with the Food and Drug Administration (FDA) and applauds your rapid response to our concerns regarding unapproved opioid analgesics. The reversal of the decision to withdraw morphine sulfate concentrates from the market will be an enormous relief to dying patients, families and caregivers throughout the country. We remain concerned that the FDA’s continued warning to manufacturers of other unapproved opioid analgesics will exacerbate current opioid analgesic supply and distribution problems. We would like to meet with you as soon as possible to discuss the effect this decision will have on hospice and palliative care patients who currently depend on these products for symptom management (notably pain and breathlessness).

The organizations that form the Coalition represent the professionals who care for more than 90% of the 1.4 million patients who receive hospice and palliative care each year in the U.S. Coalition members include:

- A. **National Hospice and Palliative Care Organization (NHPCO):** 3,000+ hospice and palliative care provider members and 37,000 healthcare professionals (NHPCO)
- B. **American Academy of Hospice and Palliative Medicine (AAHPM):** 3,700 physicians, other healthcare providers and researchers
- C. **Hospice and Palliative Nurses Association (HPNA):** 9,000+ nurses, advance practice nurses, nurse managers and researcher
- D. **Center to Advance Palliative Care (CAPC):** over 1,300 hospitals with palliative care programs

The Coalition is working with a number of other interested organizations to address FDA’s concern over unapproved opioid analgesics, while assuring that patients in pain have

uninterrupted access to required medications and receive the highest standard of care possible for symptom management.

We recognize that the recent warning letters are part of FDA's broader efforts to end the marketing of unapproved drugs – an effort that we support. Nevertheless, we view the products described in the warning letters as essential elements of effective pain management for many of our patients. These products have been used with great success for decades by providers in hospice and other settings. The consistent availability of therapeutically equivalent alternatives to unapproved pain medications that are similar in cost represents a critical element for the success of any proposed FDA action. Removing the targeted drugs from the marketplace within such a short time frame will complicate our mission to provide the most effective pain management to our patients.

Patients will suffer and experience adverse effects in the transition to other medications — even approved therapeutic equivalents. The loss of the targeted products will create a significant and disruptive impact on our ability to meet patients' needs.

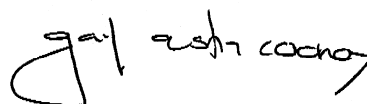
We urge the FDA to extend the time available for targeted manufacturers to undergo the approval process for both the tablet and oral concentrate forms of opioid analgesics. We also urge the FDA to implement procedures to monitor adverse patient events related to medication supply and distribution problems while the manufacturers pursue appropriate approval strategies in cooperation with the agency.

Thank you for your consideration of this matter. Please contact Judi Lund Person at NHPCO, (703) 837-1500 or jlundperson@nhpco.org to arrange for continuing dialogue with our coalition members.

Sincerely,



J. Donald Schumacher, Psy.D.
President and CEO
NHPCO



Gail Austin Cooney, MD FAAHPM
President
American Academy of Hospice and
Palliative Medicine



Margaret Campbell, PhD, RN, FAAN
President
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Diane E. Meier, MD
Director
Center to Advance Palliative Care

Cc: Joshua Sharfstein, MD, Acting Commissioner for Food and Drugs
Douglas C. Throckmorton, MD, Deputy Director, Center for Drug Evaluation and Research
Deborah M. Autor, Esq., Director, Office of Compliance, CDER