AAHPM
American Academy of
Hospice and Palliative Medicine

October 15, 2012

Margaret A. Hamburg, MD
Commissioner of Food and Drugs
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852
Division of Dockets Management (HFA–305)

Re: FDA-2012-N-0548; Drug Safety and Risk Management Advisory Committee Meeting

Dear Commissioner Hamburg,

On behalf of the nearly 5,000 members of American Academy of Hospice and Palliative Medicine (AAHPM), I am pleased to offer this response to the call for public comment regarding FDA-2012-N-0548, and ask that the Drug Safety and Risk Management Advisory Committee carefully consider the contents of this letter as they review the public health benefits and risks of drugs containing hydrocodone.

AAHPM is the professional organization for physicians specializing in hospice and palliative medicine, and our membership also includes nurses and other health care providers deeply committed to improving quality of life for patients facing life-threatening or serious conditions through the provision of palliative care. Palliative care often requires the delivery of timely and effective management of pain and other distressing symptoms. As such, we appreciate the opportunity to communicate with the FDA regarding the safe and responsible use of hydrocodone combination pain medications. AAHPM recognizes that these medications have been associated with some abuse, however they also have a proven and long-standing track record of being safe and effective analgesics for both acute and longer-term pain patients, when properly prescribed.

We are deeply concerned about and opposed to reclassification of hydrocodone-containing combination products as Schedule II controlled substances. AAHPM members are committed to stemming the tide of prescription abuse, misuse and diversion, but believe it is critical to consider the ways in which policy changes with this aim can have negative, unintended collateral effects. Medications containing hydrocodone in combination with other pain relievers are currently prescribed for both acute pain and chronic cancer and non-cancer pain, and we contend reclassification will jeopardize legitimate patient access to what has proven to be highly-effective treatment.

For example, such a reclassification will have serious adverse consequences for nursing home and hospice patients in need of immediate pain control, compounding what is already a flawed system for managing their acute pain crises. Unresolved regulatory hurdles currently result in many nursing home and hospice patients experiencing significant delays in getting needed Schedule II medications. Physicians are often not on site at these care settings and are therefore at times unable to provide written prescriptions (as required for Schedule II drugs) in a timely manner. The reclassification of hydrocodone-containing combination products will only serve to expand the scope and severity of this problem, resulting in more patients with untreated pain and experiencing what is often profound suffering.

Hydrocodone combination products are also a vital in the long-term management of chronic cancer and non-cancer pain. Yet, patients suffering moderate-to-severe chronic pain are often those least capable of meeting the increased hurdles that Schedule II drugs carry. These patients frequently have limited mobility and must be accompanied by caregivers. Since prescriptions for Schedule II medications cannot be transmitted by telephone or fax, or be refilled, the mere process of accessing them carries significant physical, financial and opportunity costs for seriously ill patients and their caregivers who will have to see a doctor for office visits with greater frequency simply to obtain a prescription. The burden will be even greater for those living in rural or underserved areas. Furthermore, and perhaps most critically, access to these medications often has substantial bearing on these patients' quality and length of life, as it allows them to complete their disease-directed treatments, sleep through the night, or continue to work and otherwise engage in and enjoy daily activities.

While we consider patient access to needed medications of paramount importance, we also recognize the need to address the public health crisis of prescription drug abuse. We believe it is essential, though, to strike the proper balance between mitigation and patient access. In that vein, it should be noted that no evidence currently exists to show that reclassifying hydrocodone will produce the desired reduction in misuse and abuse of pain medications, while evidence does exist demonstrating that rescheduling can reduce patient access to medications and cause harm. In addition, limiting access to hydrocodone combination products would leave codeine and tramadol as the only analgesics that act on opioid receptors available in the United States without the significantly increased burden of Schedule II prescribing rules. However, up to 10 percent of the American public is genetically unable to obtain analgesic effects from these two medications, making them poor alternatives for effective pain relief.

To achieve the balance we suggest, AAHPM believes that drug control policies should (1) target the sources of drug diversion, such as forgery, pharmacy thefts, and improper prescribing, and (2) focus on prescriber and patient education. Regarding the latter, it should be noted that the vast majority of prescription pain medication abusers obtain those medications from friends and family, highlighting the importance of efforts to educate patients about safe storage and the need for readily-available drug disposal programs. AAHPM stands ready to partner with the FDA and other federal agencies to develop policy that represents this balanced approach, improving public health while also preserving access to medications for patients with legitimate need.

Thank you for the opportunity to comment on this critical issue. AAHPM recognizes the public health imperative to diminish abuse, misuse and diversion of opioids and applauds the FDA's efforts to curb the illegal use of prescription drugs. We are committed to partnering with the FDA in efforts designed to enhance prescribers' knowledge and skills to improve care and outcomes for patients and improve public health and safety. At the same time, AAHPM members want to protect their patients' continued, legitimate access to medications essential to their care. Towards this end, our Academy leaders would welcome any opportunity to provide additional information or comment regarding this or any other agency initiatives, particularly with regard to the unique and important needs of patients with serious or life-threatening conditions.

Please address questions regarding AAHPM's comments to Jacqueline M. Kocinski, AAHPM Director of Health Policy and Government Relations, at jkocinski@aahpm.org or 847-375-4841.

Sincerely,

Timothy E. Quill, MD FACP FAAHPM
President