December 13, 2013

Howard K. Koh, MD, MPH
Assistant Secretary of Health
U.S. Department of Health & Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Assistant Secretary Koh:

On behalf of the undersigned organizations, we urge that you not recommend to the U.S. Drug Enforcement Administration (DEA) that hydrocodone combination products should be rescheduled from Schedule III to Schedule II unless and until the Administration and Congress act to address existing access challenges to Schedule II pain medication for medically fragile patients who receive their medication from a long-term care (LTC) pharmacy and those who are homebound and/or disabled patients. We agree with the Food and Drug Administration (FDA) and other stakeholders that there has been an alarming increase in diversion and abuse of prescription opioids and we remain committed to aggressively working with a number of stakeholders at the national and state level to combat this urgent public health crisis through a wide array of strategies. However, rescheduling at this time would significantly limit appropriate pain management of patients—particularly those in skilled nursing facilities, long-term care, rehabilitation, and assisted living facilities as well as those who are homebound or who are home limited because of illness and disability. Patients receiving care in institutional settings represent some of the most vulnerable and medically complicated populations as do those who are homebound or have a disability. We urge prompt attention to this access problem that impacts patient outcomes and contributes to human suffering. We would welcome the opportunity to work with the Administration and Congress in order to address the current barriers impeding access to Schedule II pain treatment options for this patient population prior to re-scheduling hydrocodone-containing combination products. **At a minimum, we urge you to recommend a special procedure for LTC pharmacies and pharmacists dispensing combination products if the latter are re-scheduled as well as for patients who are homebound or home limited because of illness and disability.**

Patients in Institutional Settings

For nearly five years, a cross-section of physician, pharmacist, and long-term care organizations have engaged in an effort to address a major regulatory barrier to prompt dispensing of Schedule II drugs to patients in skilled nursing facility, long-term care, rehabilitation, and assisted living facilities. During that time, LTC pharmacies have been reporting heightened enforcement action by the DEA due to the agency's interpretation of the Controlled Substances Act as precluding nurses in such facilities from acting as agents for an authorized prescriber of Schedule II drugs. As a result, a host of requirements must be met by the prescriber before a LTC pharmacy will fill and deliver a Schedule II drug.

These requirements create significant access challenges in these facilities, in contrast to a hospital or a physician's office, because the prescriber is often not on-site at the time a patient experiences an acute pain episode, when the pain medication would typically be initially ordered. Instead, such facilities are staffed by physicians who treat patients in multiple facilities. As a result, they may not be on-site and may be unable to examine a patient face-to-face immediately when the need for these medications unexpectedly arises due to acute exacerbation of a painful condition near the end of life or during transitions in care when the patient is first admitted to the facility following a hospital stay. Also, these orders are often given after hours or when the physician is traveling or otherwise in a location that is not amenable to writing and faxing a prescription. It is, therefore, not uncommon that prescribers are unable to immediately fulfill the paperwork requirements that a hard copy, practitioner-signed valid prescription be provided to the pharmacy before the drug is dispensed, particularly when a patient is suffering from acute pain. The foregoing is further complicated by the fact that this patient population is more likely than the general population to need relief from acute pain because of, for example, compromised health status, difficult to anticipate post-surgical pain profiles, and co-morbidities and complex health conditions.

The foregoing challenges are not theoretical. Physicians, nurses, pharmacists, patient groups, and others continue to report that the challenges associated with coordinating communications in order to meet the DEA requirements are substantial and onerous. Significantly, these hurdles have meant patients have faced hours, and in some cases nearly a full day, between the time that a physician determines the acute onset pain is so severe that a Schedule II pain medication is warranted and the provision of the pain medication to the patient. We are confident that these situations were not intended, but they are the result of current policies that interfere with physicians' ability to alleviate patients' pain in these settings.

As skilled nursing, LTC, rehabilitation, and assisted living facilities struggle with difficulties associated with obtaining Schedule II pain medication for their patients, the only viable alternative in many cases are Schedule III hydrocodone-containing pain medications such as Vicodin and Lortab, or transport to a hospital emergency department. Rescheduling these combination drugs from Schedule III to Schedule II without solving the current Schedule II access barriers would leave health care providers with two options: use alternative analgesics that are considerably less potent and clinically effective, or transport the patient to a hospital. Neither is acceptable medical care.

In previous congressional sessions, many stakeholder discussions occurred and legislation was drafted in an effort to resolve this problem; however, no legislation has been enacted. We urge you to join the effort to resolve the access barriers to Schedule II and, at a minimum, we strongly recommend that the HHS not recommend rescheduling hydrocodone combination pain medications until after the problem has been fully examined and is resolved.

AMDA, formerly the American Medical Directors Association, comprised of attending physicians practicing in the long term care setting, conducted a survey of its members on this topic. The results were startling:

- 91 percent of respondents said their facility has experienced delays in obtaining Schedule II controlled substance medications for patients;
- 93 percent said they had patients who experienced uncontrolled pain due to these delays;
- Half reported that these problems are a daily occurrence; and,
- One quarter said that their facility has had to send patients to the hospital to obtain Schedule II controlled substance medications because they could not obtain the necessary pain medications at the long term care facility in a timely manner.

Physicians indicated that problems most often arise with patients who are newly admitted to the facility because they lack either a temporary supply or a prescription for the medications they were taking just prior to their admission, especially if they are discharged from a hospital to the facility. Delays are also more likely with after-hours care. Delays in dispensing controlled drugs are causing needless suffering for patients who are in skilled nursing, LTC, rehabilitation, and assisted living facilities, including those in hospice care. Patients who are admitted to nursing homes to receive palliative care need to be able to count on getting that palliation, whether or not the severity of their pain has been accurately anticipated prior to their admission or during the

physician's face-to-face visit following admission. The current regulations are preventing the delivery of compassionate and quality care and need to be changed.

We have been looking for solutions and working with other professionals to try and better understand the reasons for the delays. Sometimes physician have no choice except to provide a verbal order because they are on the road without access to a fax machine or the ability to write a prescription. Physicians who attempt to call the pharmacy to speak directly with the pharmacist to meet DEA requirements may instead have to leave a voice mail message and wait for a call back. Time that pharmacists spend trying to locate physicians to return their calls is time that they are not filling prescription orders. Time that physicians spend waiting to hear back from pharmacists is time away from patient care. These lengthy delays are clearly unacceptable.

Despite efforts to engage the DEA and, more recently, Congress, reaching agreement on legislation has been stymied repeatedly by the insistence that any changes to address this problem accompany other changes to the Controlled Substances Act that would be highly punitive. We are concerned that these serious pain care access problems have persisted for years now, and we are also concerned that some of the solutions that have been proposed could further postpone their ultimate resolution. For example, solutions that would require state legislatures to adopt new laws, state pharmacy boards to adopt new rules for their states, and/or facilities and facility medical directors to assume entirely new roles with respect to pharmaceutical products beyond prescribing could take years to accomplish and could have unintended consequences. Changing federal policy is also a lengthy and complex process. In an effort to provide some immediate help to patients and physicians, those committed to compassionate and high quality long term care developed a "tip sheet" for DEA registered physicians that has been disseminated widely to the physician community to help them take steps to avoid delays in drug dispensing and make sure their patients receive treatment in a timely manner.

Homebound and Home Limited Patients

Also, we are concerned about access to medically necessary and compassionate care for another vulnerable patient population—the homebound and home limited patients. Re-scheduling combination products to Schedule II drug will create access problems for such patients—patients who by definition cannot travel to an office to get a prescription. Some clinicians are physicians, however, many house call providers are nurse practitioners and physician assistants. The majority of states restrict them from writing Schedule II drugs. The majority of house call patients are in their last two years of life and home care provides a great deal of palliative care

which often enables them to die at home. In one house call practice, for example, 2,043 patients died in the past eleven years—75 percent of whom died at home. Not only is death in the home most patients' preference, but there is an enormous cost savings for both payers and patients. Taking away the ability to call in a comfort medication such as hydrocodone will force patients to suffer or to seek relief in an emergency department, which often leads to hospitalization. The foregoing will drive-up costs, does not represent patient-centered care, and will divert scarce health care resources in the emergency department and hospital from other patients.

Patients with Disabilities

Finally, patients with disabilities face significant barriers already when attempting to access health care and often have to rely upon caregivers. While individuals with disabilities may have historically been able to count on assistance from caregivers, the ratio of caregivers to elderly people is projected to decline from roughly 7-to-1 in 2010 to less than 3-to-1 by 2050. The consequences of rescheduling combination products to Schedule II will fall heavily on individuals with disabilities and those who are involved in helping to provide them with care.

If you do recommend re-scheduling combination products, before you transmit the recommendation, we strongly urge you to consider and implement one or more of the following recommendations in order to ensure that vulnerable patient populations with medical need of Schedule II drugs do not lose access and needlessly suffer:

1) Work with the DEA to expand current nurse agent regulations to apply to Schedule II drugs;
2) Prior to re-scheduling combination products to Schedule II work with the DEA to solve this access problem to ensure there is an exception for LTC pharmacies dispensing controlled substances as well as an exception for homebound patients and those with disabilities; and,
3) Convene a stakeholder meeting to assess the impact on patients receiving medication from LTC facilities as well as the impact on home limited elderly and disabled Medicare patients of rescheduling combination products to Schedule II as any number of such beneficiaries will have significant challenges making the requisite out-patient medical appointment due to physical, cognitive, and financial limitations.

We are extremely concerned that rescheduling combination products will worsen the current barriers to adequate pain treatment for patients in skilled nursing, LTC, rehabilitation, and assisted living facilities as well as homebound and home limited patients and those with disabilities. We urge that you not recommend re-scheduling; or, alternatively, that you implement the recommendations we have outlined above before transmitting such a recommendation to the DEA. As physicians and other stakeholders, addressing human suffering and alleviating pain—particularly for those who are the most vulnerable—is an important ethical obligation and is essential to patient-centered compassionate medical care. Additional steps are needed and factors considered based on evidence and projected impact to the growing number of elderly and medically fragile patients—many of whom are ill equipped to advocate on their own behalf.

AMDA-Dedicated to Long Term Care Medicine
American Academy of Home Care Physicians (AAHCP)
American Association of Nurse Assessment Coordination (AANAC)
American Geriatrics Society (AGS)
American Health Care Association (AHCA)
American Medical Association
American Society of Consultant Pharmacists (ASCP)
National Community Pharmacist Association (NCPA)
LeadingAge
Omnicare