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Michelle Leonhart  
Administrator  
Drug Enforcement Administration  
U.S. Department of Justice  
8701 Morrissette Drive  
Springfield, VA 22152

**RE: Docket No. DEA-389, Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II**

Dear Administrator Leonhart:

On behalf of the physician and medical student members of the American Medical Association (AMA), we strongly urge the Drug Enforcement Administration (DEA) not to finalize its proposal to reschedule hydrocodone combination (HCP) medications from Schedule III to Schedule II. Among a number of critical state and federal public policies that are warranted to combat prescription drug abuse and addiction, the evidence indicates that rescheduling HCP medications from Schedule III to Schedule II is unlikely to decrease diversion, unintentional overdoses, and deaths from opioid analgesics. Instead, rescheduling will divert scarce health care resources and physician time away from delivering health care, including reducing the time health care providers have to screen for substance use disorders (including addiction to prescription drugs) and treat those suffering from addiction. As a result, we believe that rescheduling HCP is more likely to undermine efforts among health care providers and organizations to combat this public health crisis.

**PRIORITIZE EFFECTIVE STRATEGIES TO STOP PRESCRIPTION DRUG ABUSE, DIVERSION, OVERDOSE & DEATH**

The AMA continues to work with state medical associations and national medical specialty societies to combat the public health crisis created by diversion, abuse, unintentional overdose, and deaths attributable to prescription drugs. The decision to reschedule HCP medications should not be done without consideration of the public health strategies and efforts among major stakeholders to balance the need for access to pain management and identifying and treating those who are suffering from substance use disorders, including addiction. The intensity of the AMA's efforts and investment in resources have increased, as have our efforts to work with state and federal government officials, as well as other major stakeholders, to address this public health crisis. Modernization of state prescription drug monitoring programs (PDMPs) has been a major priority of physician organizations and nearly every other major stakeholder that has considered this issue in-depth. Despite broad consensus that prescribers and public health officials need these essential tools modernized to support clinical decision-making and identify

state and regional patterns of abuse and diversion, state-based PDMPs continue to have limited financial resources and interoperability (as only 25 states have adopted the Interconnect platform for data sharing). The AMA has entered into an alliance of major stakeholders to propel support for this strategy. In addition, an array of additional strategies—including prescriber education incentives, take-back programs, overdose prevention measures, such as: increased naloxone access and increased attention to coverage and access to treatment programs—are targeted and tailored to combat this public health crisis without further exacerbating the countervailing problem of under-treatment of pain.

## **EVIDENCE DOES NOT SUPPORT RESCHEDULING AS AN EFFECTIVE STRATEGY TO COMBATTING DIVERSION**

HCPs represent the most prescribed medication in the nation and yet the FDA's own analysis indicates that HCPs have lower abuse ratios than oxycodone combination products that are already Schedule II. This very strongly indicates that rescheduling HCPs may not, in fact, reduce their rates of abuse. Instead, the additional paperwork and office visits required to issue new prescriptions attendant with Schedule II drugs will re-direct staff and physician time away from delivering medical care. The FDA concluded that rescheduling HCPs could negatively impact public health and merited close monitoring. Close monitoring is not an acceptable or rational alternative to a set of public policy solutions with demonstrated efficacy in combating prescription drug abuse and diversion, such as modernized PDMPs that maintain access for those patients in need of legitimate pain management. Rescheduling is unlikely to decrease diversion, abuse, overdose, and death and is very likely to increase human suffering and morbidity among those vulnerable patients with complex medical conditions and compromised health status.

The Centers for Disease Control and Prevention estimates annually that 46 million suffer from acute pain due to surgery—and this does not even include those suffering from chronic pain. As a result, rescheduling HCP medications will have far-reaching unintended consequences. Rescheduling will divert physician focus from screening and treatment to paperwork. While the DEA may permit prescribers to issue multiple Schedule II prescriptions at the same time, up to a 90-day supply, this is not commonly utilized as state laws vary and prescribers do not want to invite undue law enforcement scrutiny through such a practice. Rescheduling HCP would be counterproductive and could very well lead to an increase in the amount of HCP medication prescribed and thereby increase the quantity of pills available for diversion. Reportedly, the usual practice among providers is to prescribe 30 tablets for a routine surgical procedure. Recent studies show that 75 percent of people will take 12 to 15. Thus, the preferred strategy is to write a prescription for 15 tablets with one refill. This will allow the 25 percent of those who need more to obtain it, and will lead to less over prescribing for the other 75 percent. If HCP medication is rescheduled, no refills can be written and phone renewals are not possible, so physicians could be more likely to prescribe the maximum in order to ensure pain is managed for all of their post-surgical patients.

The most significant threat many communities now face is increasing rates of overdose from heroin abuse. Not surprisingly, this is correlated to poorly implemented public policies that—instead of prioritizing treatment strategies—have led with across the board barriers to access to prescription drugs that are highly diverted. Restricting access to prescription drugs that are abused and diverted does not curb an individual's addiction—treatment does. At a time when the AMA and other stakeholders are focused on advancing public policies at the federal and state level to increase treatment and recovery programs and identifying strategies to increase physician participation in out-patient programs to treat addiction, rescheduling HCP medications will directly undermine these efforts.

## **RESCHEDULING WILL HARM THE MOST VULNERABLE PATIENT POPULATIONS**

Rescheduling HCP medications will 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 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. At a minimum, the DEA should establish a special procedure for long-term care 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.

**Physicians in the Long-Term Care Setting.** While every patient's medical care must be supervised by a physician, physicians are not always physically present in these facilities. Unlike in a hospital or physician's office, the prescriber is often not there when a patient experiences an acute pain episode, when the pain medication would typically be initially ordered. Very few nursing homes have staff physicians, and, often, physicians are not office-based, seeing patients in multiple facilities. In addition, orders are often given after hours or when the physician is traveling or otherwise in a location not amenable to writing and faxing a prescription to the pharmacy. Prescribers are sometimes 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 in acute pain. Thus, it is critical that a facility nurse be able to receive a physician's medication order over the telephone and act as the prescriber's agent by documenting the order in the patient's medical record and transmitting it to the long-term care pharmacy.

**Long-Term Care Facilities Differ from Hospitals.** The long-term care setting is unique in multiple ways. First, nursing facilities do not have on-site pharmacies; most contract with an outside pharmacy that specializes in serving long-term care facilities. Second, nurses play a unique role in the long-term care setting. As stated above, physicians are not often present when a patient experiences pain. The nurse is required to conduct an assessment and communicate the results of that assessment to the physician, along with other pertinent information, such as what medications the patient is currently receiving. In the normal course, the physician would then provide a telephone order to the nurse who would transcribe it to the patient's record and, acting as the agent of the physician, transmit the physician's order to the provider pharmacy. While the DEA permits hospital pharmacies to dispense controlled drugs based upon chart orders, it does not recognize chart orders when they originate from a nursing facility.

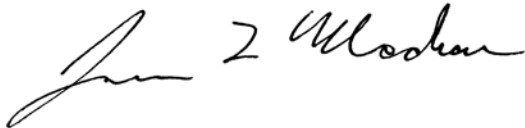
**Long-Term Care Patients are Older and More Fragile.** Long-term care patients are typically older and more medically-complex, having multiple chronic conditions and functional and cognitive limitations. They also are more likely to need palliative care and/or are suffering from a terminal illness. Long-term care residents who are treated with hydrocodone combination drugs for pain care are often hospice, cancer, or palliative care patients with physical limits like osteoarthritis or a history of fracture, and degenerative disk disease. In addition, this setting has a large population of post-acute stay patients who have just been transferred from the hospital setting after having been discharged with procedures such as hip replacements, knee surgeries, and other acute surgeries requiring pain medication. These patients are not chronic abusers of pain relievers, or diverters, but rather, are legitimate users of these

medications. This patient population is more likely than the general population to have acute pain and suffer from unresolved pain care needs.

Despite representations that there is a solution to the foregoing access barriers to Schedule II medications, the reality is that physicians, patients, and other stakeholders including long-term care pharmacies, are continuing to report that these barriers remain. There is a broad consensus among every stakeholder in this space that the current DEA regulations and enforcement activities have contributed to insurmountable barriers to accessing Schedule II medications for patients in acute pain. At a minimum, we strongly urge the DEA to work in concert with the U.S. Department of Health & Human Services to address the existing barriers to accessing Schedule II medications currently faced by the most vulnerable patient populations that will be further exacerbated if HCP medications are re-scheduled.

**The AMA strongly urges that the DEA not finalize the proposed rule to reschedule HCP medications.** We appreciate the opportunity to comment and look forward to working closely with the DEA to implement policies and strategies that are likely to reverse overdose and death, including increasing the availability of take-back programs and treatment and recovery in out-patient settings.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is written in a cursive, flowing style.

James L. Madara, MD