April 28, 2014

Michele M. Leonhart
Administrator
Drug Enforcement Administration
Attention: DEA Federal Register Representative/ODW
8701 Morrissette Drive
Springfield, VA  22152

Re:  Docket No. DEA-389 – Schedules of Proposed Substances: Rescheduling of Hydrocodone Combination Products From Schedule III to Schedule II
79 Fed. Reg. 11037 (Feb. 27, 2014)

Dear Administrator Leonhart:

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

The undersigned organizations, members of the Patient Quality of Life Coalition, submit these comments to the Drug Enforcement Administration (DEA) of the United States Department of Justice. The Patient Quality of Life Coalition advances the interests of patients and families facing serious illness, including survivors. The Coalition includes more than 20 nongovernmental organizations dedicated to improving patient quality of care.

The misuse and diversion of hydrocodone combination products (HCPs) is a significant public health concern that merits efforts to mitigate associated harms. Practitioners responsible for alleviating patient suffering, however, do not support rescheduling as a means to mitigate those harms. Rescheduling will undoubtedly make treating the pain of persons with serious illness more difficult whereby causing setbacks in therapy and accelerating their suffering, particularly as the illness advances and at the end of life. The quality of life of persons with advanced, serious, and chronic illnesses will be adversely affected at a time when pain relief is critical and necessary. Rescheduling focuses only on the reduction of improper use, fundamentally ignoring the substantial public health concern posed by poorly-treated and unrelieved pain. Rescheduling will create unintended hurdles to legitimate access and use of HCPs. The Coalition strongly opposes rescheduling of HCPs. If this rule is finalized, however, we urge the rescheduling to be accompanied by robust monitoring systems to evaluate the effects of rescheduling on patient access to HCPs, and we further request the DEA along with the Department of Health and Human Services commit to additional steps in order to quickly remedy any patient access issues revealed through monitoring.
Background

Testimony at the US Food and Drug Administration’s (FDA’s) advisory committee hearing on this proposal revealed that HCPs represent the most prescribed medication in the United States, with more than 130 million prescriptions issued to 47 million patients in 2011. That testimony also indicated that the majority of HCP prescriptions appear to be for acute pain, as the median number of days’ supply for HCP prescriptions was eight. The most common diagnoses associated with HCP prescriptions were musculoskeletal system and connective tissue diseases (25% of prescriptions); respiratory system diseases (21% of prescriptions); and fractures, sprains, contusions, and injuries (19% of prescriptions). Primary care practitioners also issued about 40% of all HCP prescriptions1. Further, although this number did not appear in the meeting materials, FDA staff informed the Advisory Committee that approximately 20% of all HCP prescriptions in 2011 (or about 26 million) were refills of prescriptions previously issued.

When FDA staff conducted data analyses to determine the extent to which HCPs are abused, comparisons were drawn to oxycodone combination products, immediate-release oxycodone, and extended-release oxycodone, all of which are already in Schedule II. FDA’s presentation at the advisory committee hearing indicated that the answer to the question as to which is most often abused depends a great deal on the specific numerators and denominators chosen for the analyses. In the end, based on the indicators chosen by FDA staff, the conclusion presented to the committee was that HCPs have lower abuse ratios than oxycodone combination products, despite a much larger volume of prescriptions, and thus availability, of HCPs1. We note that this is despite the oxycodone combination products residing in Schedule II, which suggests to us that rescheduling HCPs may not, in fact, reduce their rates of abuse.

After two days of testimony, the advisory committee ultimately voted, 19-10, to recommend that HCPs be rescheduled into Schedule II. During the discussion following the vote, committee members’ comments were notable for two common sentiments: 1) many expressed doubts that rescheduling would reduce HCP abuse, and, instead, might drive an increase in heroin abuse; and, 2) having been asked to vote “yes” or “no” on a recommendation for rescheduling, many expressed a wish that they had a third option that might be at least equally effective and less likely to inappropriately restrict access for patients who need HCPs to treat pain.

The FDA’s eight-factor analysis of the proposed rescheduling, developed after the advisory committee meeting, concluded that rescheduling HCPs could negatively impact public health and merited close monitoring:

“Finally, to return to the comments above about the limitations of the available data, FDA recommends close continued monitoring to assess the impact of this action on the public health, especially given the concerns that were voiced by many individuals and groups about the impact of this up scheduling on access. New strategies, data, and analytic tools will be needed to accomplish this, including the need for new tools to assess the impact of policy changes on appropriate access to pain medicines by patients with pain. Given the importance of both addressing the appropriate treatment of pain and the personal and societal costs of abuse and misuse of opioids, including hydrocodone, it is critical that we identify better tools for predicting and assessing the impacts of decisions such as the up scheduling of hydrocodone combination products on public health.”

Conclusions about restricted access

As signatories to this letter, we share the advisory committee members’ concerns that rescheduling HCPs will erect significant barriers to access for persons with pain, especially those with serious illness and at the end of their lives. We are concerned that there may be at least three such barriers resulting from rescheduling:

1) **Lack of access to refills.** If HCPs are rescheduled, refills will no longer be permitted, and new prescriptions will not be permitted by telephone or fax. Patients suffering moderate-to-severe chronic pain frequently have limited mobility and must be accompanied by a caregiver. Requiring patients with chronic and/or serious illness to make several additional trips to the prescriber’s office each year carries a significant physical and financial burden. At the same time, the healthcare system will be required to accommodate some portion of 26 million additional written prescriptions each year. Our healthcare system, especially the primary care sector of it, is already overburdened and straining to handle the current volume of patient visits. If patients are required to obtain up to 26 million written prescriptions that previously were automatically refilled at the pharmacy, it will produce a significant additional burden for prescribers, pharmacies, and patients. Further, if prescribers (who are already anxious about regulatory scrutiny of opioid prescribing) require a substantial portion of these patients to be seen in clinic before issuing a new prescription, the potential cost could run into the hundreds of millions of dollars per year.

2) **Prescribers unwilling or unable to prescribe HCPs if they are rescheduled.** Increasingly, prescribers are expressing concerns about regulatory scrutiny attached to opioid prescribing. In response to those concerns, some are instituting policies within their practices that prohibit prescribing of Schedule II medications. Additionally, there are a number of states where “non-physician” prescribers, including nurse practitioners, physician assistants, optometrists, and others, are prohibited by state law from prescribing Schedule II medications. In Texas, for instance, nurse practitioners are subject to such a prohibition. These non-physician providers are responsible for a substantial volume of routine patient visits in primary care settings, and undoubtedly for a substantial volume of HCP prescriptions, as well. A prescribing limitation will result in prescribing alternatives, many of which are not recommended, suitable, or adequate replacements to HCPs. Prescribers may turn to codeine and tramadol, for example, which are not recommended or reflective of current best practices because both are notable for substantial side effect profiles and the potential, especially for codeine, for decreased analgesia. In addition, up to 10 percent of the American public is genetically unable to obtain analgesic effects from these to medications, making them poor alternatives for effective pain relief.

3) **Decreased availability of the medication at the retail pharmacy level.** Rescheduling HCPs to Schedule II would require that these medications be stored in more secure conditions within pharmacies and throughout the distribution chain. This means that wholesale distributors will need to increase the size of their secure warehouse storage areas, and that retail pharmacies may need to increase the size of their controlled substance vaults, both of which will cost millions of dollars. The volume of medication that would need to be accommodated in this process is very substantial, and it simply may not be possible for retail pharmacies, in particular, to expand their storage enough to accommodate their current volume of HCPs. Faced with these circumstances, it is possible that retail pharmacies will order less of the medication, and that wholesale distributors will ship less of the medication, potentially creating shortages for patients who need it to treat pain.
In conclusion, we reiterate our opposition to rescheduling and reemphasize the need to monitor the effects of this proposed policy change. We share a concern for how HCPs affect public health. However, we ask the DEA to recognize that access to, and the legitimate use of, HCPs have a positive contribution to the nation’s public health and that this contribution be given equal weight to the goal of curbing inappropriate use.

Sincerely,

American Academy of Hospice and Palliative Medicine
American Academy of Pain Management
American Cancer Society Cancer Action Network
C-Change
Cancer Support Community
Center to Advance Palliative Care
CHE Trinity Health
Colon Cancer Alliance
Hospice and Palliative Nurses Association
Lung Cancer Alliance
National Coalition for Hospice and Palliative Care
Supportive Care Coalition