April 28, 2014

Michele M. Leonhart
DEA Administrator
Drug Enforcement Administration (DEA)
8701 Morrissette Drive
Springfield, VA22152

Re: Docket No. DEA-2014-0005-0004 - Schedules of Controlled Substances:
Rescheduling of Hydrocodone Combination Products from Schedule III to
Schedule II

Dear Mrs. Leonhart:

On behalf of more than 18,000 board-certified orthopaedic surgeons in the United
States, the American Academy of Orthopaedic Surgeons (AAOS) thanks the DEA
for the opportunity to comment on the proposed rescheduling of hydrocodone
containing products (HCPs) from a Schedule III narcotic to a Schedule II narcotic.

The AAOS shares the concerns of the DEA regarding inappropriate use of
opioid/narcotic medications including HCPs. The AAOS is aware that opioid
consumption in the United States (US) is increasing and patterns of use are
different than other countries. The AAOS believes that educating US physicians
and patients is the best way to reduce opioid/narcotic consumption and change
patterns of misuse.

Recognizing the urgency of this public health problem and the important roles
that physicians have in controlling appropriate use of opioid medications, the
AAOS has initiated a comprehensive education program on this topic for its
members including annual meeting symposia, webinars and scientific articles.

It is important for the DEA to be aware of the significant responsibilities that
orthopaedic surgeons and other caregivers face in the management of pain
associated with many common acute and chronic musculoskeletal conditions.
Painful musculoskeletal conditions represent the most common reasons why
patients seek medical attention in primary care physicians’ offices and in
musculoskeletal specialists’ offices, including orthopaedic surgeons, urgent care
centers and emergency rooms.

Currently, US pain management efforts after injury and/or surgery is focused
almost entirely on use of opioids/narcotics - accounting for >80% of the world’s
prescription opioid/narcotic medication consumption. Most US patients expect pain to be avoided or eliminated through the use of opioid/narcotic medications. Evidence is emerging that use of effective coping strategies and limiting psychological distress are as or more effective for pain relief/management. Neither is enhanced by opioids/narcotics. Future pain patients can benefit from pain management strategies which decrease/limit opioid use and include cognitive behavioral therapies prior to elective/discretionary surgeries. Similarly, techniques for effective pain management after injury can be improved with better pain coping strategies and increasing use of non-narcotic pain relievers/modifiers.

It is also important for the DEA to be aware that adequate pain management is an important component of patient satisfaction. Fearing adverse ratings, some physicians are incented to use or continue use of opioid/narcotic medications. Physician performance is increasingly being evaluated based on patient satisfaction scores, some of which are linked to reimbursement. Having effective alternative programs in place to better manage patient expectations during stressful health transitions will be essential in affecting change in physician and patient behavior.

Dissatisfied patients often exhibit stressful and disruptive behaviors leading to increased and unnecessary costs for evening care/weekend phone calls, added office visits and increased visits to urgent care centers/ERs for pain management. Rural patients especially will incur increased costs and inconvenience. If, in our current climate, HCPs are reclassified as Schedule II drugs requiring only physician written prescriptions without other supportive pain management options, physicians and surgeons may in fact prescribe larger numbers of pills/prescriptions in an attempt to effectively manage patient pain outside office hours and to limit/control calls and complaints – having the unintended consequence of increasing the risk of opioid misuse and diversion.

Significant time, resources and commitment of regulatory, legislative, health policy and medical professional organizations will be needed to change the pattern of US opioid/narcotic consumption. The AAOS recommends that the DEA work with the AAOS and other important stakeholder organizations to implement a comprehensive opioid/narcotic medication use/misuse program to address and modify these cultural norms and behaviors. Isolated reclassification of hydrocodone (HCPs) to Schedule II will have little or no impact on opioid use/misuse and in fact may lead to an unintended increase of use, misuse and diversion.
For additional information or clarification please do not hesitate to contact the Medical Director in our Washington office, William O. Shaffer, MD, at (202) 546-4430 or shaffer@aaos.org.

Sincerely,

Frederick M. Azar, M.D.
President, American Academy of Orthopaedic Surgeons