



AMERICAN ACADEMY OF  
ORTHOPAEDIC SURGEONS

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ORTHOPAEDIC SURGEONS

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[www.aaos.org](http://www.aaos.org)

June 27, 2013

Margaret A. Hamburg, MD  
FDA Commissioner  
Food and Drug Administration (FDA)  
10903 New Hampshire Ave.  
Silver Spring, MD 20993

Dear Dr. Hamburg:

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

In January FDA's Drug Safety and Risk Management Advisory Committee voted 19 to 10 in favor of rescheduling hydrocodone-containing compounds from Schedule III drugs under the Controlled Substances Act to Schedule II. The decision to reschedule now rests at the FDA.

The appropriate use of opioid analgesics is a legitimate concern of the AAOS and a focus of study and communication by our Patient Safety Committee. This has taken many forms including published articles in our literature and website intended for our members and their patients. We recently produced a Webinar for our members on this exact subject.

We believe that potential for misuse, long-term risk of abuse, and criminal diversion of prescription narcotics are also issues that require a multifaceted approach including physician and patient education, law enforcement measures, state reporting systems such as the Kentucky All Schedule Prescription Electronic Reporting (KASPER) system, and the cooperation and disciplined authority of state pharmacy and medical licensing boards. When illegitimate patients and non-therapeutic prescribers and dispensers violate the law, act unprofessionally, or fail to adhere to the rules of their licensure; the AAOS supports law enforcement and licensing board action targeted at the offenders.

Orthopaedic surgeons are called upon daily to treat some of the most acutely painful conditions of the human body, including injuries and surgery of the musculoskeletal system. The ability to appropriately use powerful medications including opioid analgesics in these settings is an essential component of



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optimal healthcare. With the FDA withdrawal of Darvocet and Darvon and concerns regarding the seizure risk of Demerol, Hydrocodone compounds have become the mainstay for management of our patients' acute pain exceeding that controlled with non-narcotic pain medication.

Despite the widespread use and promotion of Electronic Health/Medical Records, Class III compounds cannot be eScribed, but they can be eFaxed as well as prescribed by regular written or telephonic means including refills. Reclassification to Schedule II would significantly inconvenience many patients in acute pain and move the collection of prescription data in the EMR/EHR further away from the desired goal of electronic reporting. The AAOS supports accountability and surveillance of prescribing patterns through electronic prescribing in all states for all schedules, including Class II through V.

Schedule II drugs now require a special written prescription without an option to refill. Reclassification will purposely inconvenience and delay legitimate acute pain patients access to controlling their symptoms at additional and avoidable cost to the individual and healthcare system. Rural patients will be most affected, but all will be required to wait for a mailed prescription or to schedule and travel to another doctor appointment in order to simply receive a written refill authorization, let alone a new prescription. This also invites the potential for increased use of the ED, simply to obtain a legitimate refill after clinic hours.

There are several potential unintended consequences of reclassifying hydrocodone to Schedule II. First, prescribers required to write a special prescription might have a lower threshold to use of other Schedule II opioids with a greater potential for abuse, addiction, patient harm, and criminal activity. Second, prescribers unable to provide refills of these medications may prescribe a greater dose and/or number in order to not inconvenience the patient, putting more pills into the community for potential misuse and diversion. These unintended consequences of reclassification could fuel the fire of the very epidemic that proponents of reclassification seek to mitigate.

The AAOS urges the FDA to maintain the current Schedule III classification of Hydrocodone compounds. We further urge the agency to work with professional medical, surgical and pharmacy associations such as ours to educate and communicate to professionals, patients, and the public, regarding the optimal effective and safe means to control acute pain, as well as the potential harm of use of opioid analgesics in the chronic pain patient. Lastly, we offer our support for design and implementation of interlinked state surveillance systems that report all narcotic prescriptions including use of electronic prescribing through the EMR/EHR, for use by law enforcement and



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the licensing boards of prescribers and those that dispense these pharmaceuticals inappropriately or illegally.

Sincerely,

A handwritten signature in black ink, appearing to read 'Joshua J. Jacobs'.

Joshua J. Jacobs, MD  
President, American Academy of Orthopaedic Surgeons