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RE: FDA-2012-N-0548

Nearly 90,000 certified physician assistants (PAs) are represented by the American Academy of Physician Assistants (AAPA). The Academy is concerned regarding proposals to re-categorize all hydrocodone containing substances and combinations as Schedule II drug classification.

AAPA acknowledges the serious problem of diversion and abuse of opioid drugs. However, the Academy believes that diversion and abuse of opioid drugs ought not be addressed by limiting access to opioids that can be used to safely and effectively manage patients' pain. It is questionable whether rescheduling the drug to the Schedule II classification would significantly alter diversion and abuse. However, rescheduling the drug would most certainly limit access to individuals who may benefit from its use by limiting the number of healthcare professionals who can prescribe it and through the imposition of additional barriers associated with Schedule II drugs, such as the inability to phone in prescriptions or refill the prescription.

In its 2011 report, "Relieving Pain in America," the Institute of Medicine states that the magnitude of pain experienced by Americans is a human and economic crisis. The IOM estimates that over 100 million Americans suffer from chronic pain alone and that pain costs the U.S. \$635 billion each year in medical treatment and lost productivity. The report does not suggest limiting access to opioids or other pain medication, but, rather recommends a comprehensive strategy of public education, research, data collection, and advanced educational preparation of healthcare professionals to confront pain prevention and management.

Physician Assistants may currently prescribe Schedule II medications in all but 14 states. Accordingly, the proposed rescheduling of hydrocodone containing substances and combinations to Schedule II classification will not widely limit PAs' ability to prescribe the pain medication. However, it will limit access to appropriate pain medication for patients with legitimate clinical need.

AAPA stands ready to work with the FDA to develop legislative policy to address the diversion and abuse of hydrocodone containing substances and combinations. In the meantime, however, we urge the agency not to limit access to appropriate pain medication.

Please do not hesitate to contact Sandy Harding, AAPA senior director of federal advocacy at sharding@aapa.org or 571-319-4338 with questions regarding the PA profession or the Academy's comments.

