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American Academy of
Physical Medicine and Rehabilitation

Written Statement of the

American Academy of Physical Medicine and Rehabilitation (AAPM&R)

Before the Food and Drug Administration (FDA), Health and Human Services (HHS)

On the Impact of Approved Drug Labeling on Chronic Opiate Therapy

Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, Maryland

February 8, 2013

Commissioner Margaret A. Hamburg, M.D.:

Thank you for the opportunity to comment on issues pertaining to impact of approved drug labeling on chronic opiate therapy on behalf of the American Academy of Physical Medicine and Rehabilitation (AAPM&R), which is the national association representing more than 8,000 physical medicine and rehabilitation physicians, known as physiatrists. Our physician members strive to ensure safe and effective prescribing to improve patient care and safety while minimizing risk. Our specialty is leading the charge to effectively manage clinical and practice issues around pain management, specifically long-acting and extended-release opioids.

The AAPM&R is the only national physician specialty organization committed exclusively to serving the needs of people with a wide range of disabilities and chronic conditions, including pain. Physiatrists treat adults and children with acute and chronic pain, musculoskeletal, neurologic and rheumatologic disorders, persons who have experienced catastrophic events resulting in paraplegia, quadriplegia, traumatic brain injury, spinal cord injury, limb amputations, or any other disease process that results in impairment or disability.

The nature of our specialty implies that our patients have pursued appropriate acute and subacute care, but continue to carry pathophysiology that prevents them from functioning normally. Specifically, patients with chronic pain who present to physiatrists have almost always demonstrated an objective pathological lesion and have failed a number of interventions. Additionally these patients have suffered a loss of function associated with diffuse psychosocial problems.

Physiatrists are committed to effectively managing the complex clinical, functional and psychosocial issues associated with chronic pain management. Our goal is always the restoration of function by minimizing pain.

It is our philosophy to first approach a patient's functional status and design a means of obtaining functional goals rather than approaching a patient's symptomatology. This comes about through a process of shared decision-making between the patient and his or her physiatrist. From the beginning of care, a physiatrist educates his or her patient to understand that a patient must first bear responsibility for their situation and must understand the pathological process, potential treatment options including risks, benefits and alternatives, and most importantly understand that the goal is to restore function, not eliminate pain.

The AAPM&R and its members share the concerns with many in this country about how to balance the use of potentially high-risk narcotics to maximize our patients' functional capacity with the effect that the misuse of these medications has on individual patients, their families and our society.

We believe that physician education, including the recently FDA-mandated Risk Evaluation and Mitigation Strategies for the safe use of opiate analgesics continues to be the most effective means of decreasing the risk of morbidity associated with the use of opiate analgesics.

However, we are also concerned that well-meaning regulatory intervention will invariably lead to unintended consequences that will unfairly affect some of Medicare and Medicaid's most vulnerable beneficiaries—individuals already struggling with chronic disability.

The three areas of greatest concern to our specialty on behalf of our patients are the arbitrary determination of mild, moderate and severe pain, limiting the use of opiates to 90 days and codifying a maximum daily morphine equivalent dosage.

The use of such subjective terms as mild, moderate or severe is problematic because it is arbitrary. The language allows significant interpretation, and therefore can and will be used by patients and physicians to gain access to what they perceive as being appropriate treatment, but will also lead to unnecessary suffering through undertreatment.

Physicians tend to agree that there is variability in pain intensity over the continuum of chronic nonmalignant pain. Pain may be moderate during periods of rest but frequently becomes severe when a patient is physically active. Patients are frequently treated with an opiate in anticipation of physical activity thereby maximizing function by minimizing the impact of pain. This is most appropriately accomplished by using regularly scheduled sustained-release opiates.

Likewise, opiates provided for longer than 90 days are effective for carefully selected patients. To assume that a patient with chronic nonmalignant pain will spontaneously achieve relief of their symptoms in 90 days denies currently accepted pathophysiology and clinical experience.

It is our position that in appropriate cases the use of sustained-release opiates in nonmalignant chronic pain has the potential of maximizing function and quality of life, decreasing the risk of depression, anxiety and deconditioning commonly observed in these patients. In addition, in carefully selected patients the prolonged use of sustained-release opiates may reduce the risk of abuse and addiction over short-acting opiates when used for nonmalignant chronic pain.

Our third concern regards establishing a maximum daily morphine equivalent. Universal population-based conversion tables utilized to determine equivalent morphine doses in patients treated with non-morphine opioids differ widely and are based on heterogeneous groups of patients, including those of various ages and with a variety of medical comorbidities.

Significant clinical experience supports patient variances in the analgesic effect of opiates and opioids, and pharmacokinetic differences are clearly proven to exist among patients. Therefore, an arbitrary cap on a daily dose based on morphine equivalents for nonmalignant chronic pain would not serve treatment needs across the spectrum of patients. In fact, recent literature

suggests a nonlinear opiate variability, calling into question the accuracy of morphine equivalent conversion paradigms.

Just as important, such a cap could provide a false sense of security for those clinicians using doses lower than 100mg morphine equivalents. Serious adverse events including respiratory depression, cognitive impairment, addiction and sudden death have been demonstrated in opiate doses below 100mg equivalents.

The AAPM&R appreciates the opportunity to comment on the use of opiates in the treatment of chronic pain. Our Academy strongly supports the national search for meaningful solutions to reduce opiate-related harm and ensure public safety. Our focus should never waver from improving the education of clinicians, not only on opiate prescribing, but also with an assessment and treatment of pain that incorporates patients in a shared-decision-making process that results in clearly defined functional goals and improved quality of life.

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