March 12, 2013

Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dear Officers of the Food and Drug Administration:

Re: Food and Drug Administration [Docket No. FDA–2012–N–1172] Impact of Approved Drug Labeling on Chronic Opioid Therapy

The Gerontological Society of America (GSA) is pleased to submit these comments in response to the Food and Drug Administration (FDA) December 19, 2012 Federal Register Notice of Public Hearing and Request for comments on the Impact of Approved Drug Labeling on Chronic Opioid Therapy. GSA is the largest multi-disciplinary professional membership organization of researchers studying all facets of aging on a national and international scale. The Society's members include physicians, nurses, biologists, psychologists, social workers, economists, health policy experts, and others interested in expanding scientific knowledge related to aging. Because of the breadth and depth of our members’ interests and scholarship in gerontology and geriatric practice, GSA’s strengths in this knowledge domain may be of benefit to the FDA in developing its position on opioid therapy as it concerns older adults’ unique needs. The following comments have been developed with input from GSA members in medicine, nursing, health policy, social work and the law, and ethics.

Pain Management Needs of Older Adults

The pain management needs of older adults are of paramount concern to our organization. In the fall of 2011, GSA issued two special publications to our members, the first highlighting the Institute of Medicine’s (IOM) groundbreaking report, Relieving Pain in America (2011), and the second focusing on the FDA’s changes on acetaminophen dosing and the impact of those changes on older adults. This past year we published a special report on studies of pain in older adults by GSA members.

In light of this high level of engagement by our members in issues that concern older adults’ access to adequate pain management, GSA continues to be mindful of the FDA’s oversight role and commitment to minimizing the risk of opioid drug abuse, diversion, and misuse as stated in its Federal Register Notice. We are also aware of the steps taken by the FDA in July 2012 resulting in approval of the Risk Evaluation Management Strategy for extended-release and long-acting opioid analgesics.

Generally, it is the position of GSA at this time that existing regulatory structures and safeguards are adequate to protect older adults from potential threats and risks posed by drug abuse and drug diversion. State policy and regulation are robust in this area. Most states have prescription monitoring programs (Deyo et al., 2013), and many require training for health care practitioners in pain management to assure that patients receive comprehensive pain assessment and adequate pain management. A critical issue for the older adult population is engaging in care planning and establishing appropriate goals of care including pain management goals. Goals of care and care planning should
guide decision making about older adults’ pain and analgesic needs. If more resources are invested in pain programs, they should be invested in additional training for health care practitioners to strengthen their pain assessment and pain management skills.

In keeping with the principle of balance established by the United Nations’ Single Convention on Narcotic Drugs of 1961 (Single Convention, 1961) that promotes dual goals of public health and public safety, GSA is opposed to broad-based restrictions on opioids that would have a deleterious impact on older adults’ access to pain care, and likely a chilling effect on health care practitioners’ prescribing practices. Instead, GSA supports a public health approach to the complex issue of non-medical use of prescription opioids and the promotion of intersectoral collaboration to address the identification of sources and targeted interventions, the unintended effects of proposed restrictions, and more effective utilization of existing drug control programs within a clear framework and understanding of the authority to regulate medical practice.

There are also unintended downstream consequences of limiting access to opioids for older adults such as hindering high-quality palliative and end-of-life care for seriously ill patients. Restrictions in prescribing practices for those with severe chronic or life-limiting illness will disproportionately impact older adults. Research shows a strong association between chronic illness, multimorbidity and pain prevalence and intensity, especially among aging Americans (Atlas & Skinner, 2010; IOM, 2011). Another critical factor is that the use of these drugs is not limited to the treatment of pain; opioids are also used in the management of highly-burdensome symptoms such as shortness of breath (American Geriatrics Society [AGS], 2012), which plays an important role in effective symptom management for a very sick population. Proposed restrictions on access to opioids would impact quality symptom management goals for individuals with chronic and end-stage cardiopulmonary disease, cancers, and other advanced stage diseases.

Comments on Section B. Understanding and Adhering to the Labels of Pain-Treating Products

The fastest growing segment of the population is those over 65 years, with 10,000 new persons achieving this landmark each day (Administration on Aging, 2012). By 2030, our health care system will be challenged by 75 million older adults, many of whom have multiple chronic conditions. Chronic diseases, including cardiovascular disease, diabetes mellitus, degenerative joint disease, osteoporosis, cancer, and peripheral neuropathies, are more prevalent in older adults and are often associated with persistent pain problems (Bruckenthal, Reid & Reisner, 2009).

Pain is a common enemy of older persons with the prevalence of persistent pain ranging from 25-50% in community dwelling (MacFarlane, 2011; Tsai, Liu, Chung SC, 2010) and 50-85% in institutionalized older adults (Smith, Cenzer, et al., 2010; Tse, Leung & Ho, 2012). Untreated or ineffectively treated moderate to severe persistent pain can cause great harm in older persons, resulting in loss of functional independence, disability and impaired physical function, impaired social interactions, increased anxiety and depression, impaired cognitive function, altered nutrition and sleep and overall decreased quality of life—all contributing to increased use of health care resources and costs (Griffin, Harmon & Kennedy, 2012; IOM, 2011; Johansen, et al 2012; Shega et al., 2012). Disparities in pain management for vulnerable elderly persons have been widely recognized as a public health problem (Mayday Fund, 2009; IOM, 2011).
Clinicians caring for older adults with persistent pain are particularly challenged to balance concerns about medication harms with benefits to function and quality of life. Additionally, older persons are more vulnerable to both the potential harm of unrelieved pain and the medications used to treat it (Arnstein & Herr, in press). Increased vulnerability to side effects and drug interactions exist in older persons due to differences in drug distribution, metabolism and elimination (Gupta & Avram, 2012; Milton et al., 2008), as well as the challenges of multiple comorbid conditions and polypharmacy (Evans et al., 2012). Analgesics are integral to treatment of moderate to severe pain, yet most drugs contain some element of heightened risk in older adults (Brandt, Hanna & Walters, 2013). Thus, clinicians need an armamentarium of options that can be considered based on the unique circumstances of each older person. With appropriate precautions (AGS, 2009), analgesics can be part of a comprehensive treatment plan in older adults that is based on a careful evaluation of risk/benefit, includes planned reassessment and monitoring of outcomes, and incorporates nonpharmacological and alternative interventions along with analgesic treatment.

Impaired cardiovascular, renal, and/or hepatic function, along with increased risk of gastrointestinal bleeding, impact safe choices of analgesics in this population. Nonopioids can be effective in managing mild and some moderate pain, but for those with greater discomfort stronger treatment options are often necessary. Non-Steroidal Anti-inflammatory Drugs (NSAIDs) can damage these end-organs, and thus in the recently published Beers Criteria (AGS, 2012) it is strongly recommended that NSAIDs be avoided in patients with heart failure, chronic renal diseases, and in patients with a history of peptic ulcer disease. Opioids are recommended as an option for consideration in moderate to severe persistent pain not responding to other approaches, following a careful risk/benefit analysis of pain and its impact, pain goals, and risks of treatment (AGS, 2009). A comprehensive assessment and individualized treatment plan should include careful consideration of available treatment options, both drug and nondrug, and is determined in conjunction with patient preferences and values.

Opioids can be used safely in older adults with careful patient selection, monitoring and use of risk reduction strategies (Arnstein & Herr, in press). Further, concerns regarding drug diversion and opioid abuse have not been established in the older population without a prior history of substance abuse, and certain studies show a significant association between older age and lower risk for opioid misuse and abuse (AGS, 2009; Ives, Cheilminski, Hammett-Stabler, et al., 2006; Reid, Engles-Horton, Weber, et al., 2002). Although there is limited evidence of risk of aberrant behavior, the possibility of such a risk can be addressed through careful treatment planning and monitoring—risk evaluation and mitigation. In addition, strategies for managing opioid use are available including the potential broader utilization of the CMS Medication Therapy Management Program to provide patient education and monitoring (CMS, 2010), the FDA Risk Evaluation Mitigation Strategies (REMS) for ER/LA opioids, and other opioid monitoring programs such as instituted by the states (Deyo et al., 2013).

Comments on Section C. Limiting Opioid Prescription and Use

Restriction of opioids to only severe pain eliminates one treatment option that may be the safest approach for many older persons suffering with chronic pain. All drugs should be used with caution and with appropriate determination of medical necessity. Decisions about appropriate analgesic use should
be tailored to the individual’s pain type, risk factors, personal preferences, ability to adhere to treatment and should be determined by the health care provider in conjunction with personal preferences and values. Studies have documented functional impact from moderate pain, not just severe, that can seriously affect the quality of life of our elders. Because of unique responses to pain, people experience pain differently, but similar levels of pain can have dramatically different impacts depending on the individual’s experiences, personal characteristics, coping ability, attitudes and beliefs. Establishing an indication for opioid use for severe pain only, or a maximum dose and/or duration for opioid use, discounts the older person’s unique experience of pain, response to pain and response to treatment. A one-size-fits-all approach is not appropriate for pain management. Therefore, it cannot be blindly applied across all people experiencing a certain chronic disease or level of pain severity. Treatment must be tailored to the individual older adult and health care providers need an armamentarium of potential treatment options that can be used depending on the comorbidities and risks of the older person.

Opioid medications are also important in managing chronic and acute symptoms of breathlessness (shortness of breath/dyspnea) experienced by many individuals with chronic cardiopulmonary diseases including congestive heart failure, chronic obstructive pulmonary disease, and pulmonary fibrosis. Approval of the recommended limits on opioid therapy options proposed in this petition could have profound consequences for older adults leading to greater suffering and adverse consequences. If stricter limitations are imposed, it is likely that the fear of opioids that already exists among providers and older persons will be heightened and access to strong treatments will be difficult to obtain by those who need them.

Ethical Issues: Person-Centered and Humanistic Care

GSA wishes to draw particular attention to the risks inherent in any approach to regulation of opioids that involves biological reductionism and does not take account of the health and well being of older adults as human persons who are fully engaged until the end of their lives in processes of human development and resilience. Evaluation of pain that is based solely on biology, identification of disease etiology, and measurement of pain intensity will exclude large domains of pain and suffering experience and analgesic needs in the older adult population. The paradigmatic case of a frail elderly patient with advanced dementia who has multiple chronic conditions and contractures, has lost the capacity to communicate, and moans and groans persistently, demonstrates the challenges of relieving pain for the suffering older adult for whom there may not be a well-established causal explanation. Although evidence-based tools are available for assessing pain in such nonverbal cases, in light of the challenges identified in the assessment, evaluation, and treatment of pain in older adults, GSA calls for more humanistic responses to the pain experiences of older adults that will be sensitive to older adults’ social ecological contexts and person-centered care needs (Morrissey, 2011), and effective in enabling access to comprehensive assessment and multimodal treatment.

Recommendations: Interdisciplinary Research, Education and Training

Interdisciplinary approaches to pain management are necessary to optimize the health and well-being of older adults (Berkman, 2011; IOM, 2011; Mayday Fund, 2009) who often have complex health care and palliative needs. For older adults who are living through experiences of pain and serious illness, the primary goals of effective pain management are to protect their dignity, maintain or improve function, optimize quality of life, reduce pain levels, prevent and relieve suffering, and respect their
values and preferences in the treatment plan. Pain management is recognized as one of the major and essential pillars of a palliative care approach to person-centered and geriatric care (National Consensus Project, 2009). Both the American Geriatrics Society (AGS, 2009) and the Institute of Medicine (IOM, 2011) have been instrumental in bringing national attention to this critical issue affecting the public health. Among the recommendations of the IOM that are critically important to the care of older adults are enabling self-management of pain, eliminating barriers to adequate pain care, and promoting interdisciplinary research and training for those who are conducting research on pain.

The call in the IOM Report (IOM, 2011) for improvements in pain care are timely and appropriate given the urgent and oftentimes neglected needs of vulnerable older adults. This transformation extends to the interdisciplinary professional community. Specialists in pain and palliative medicine as well as generalists need to receive ongoing training in principles of pain assessment and pain management, and spend time educating the older adults they serve about the complexities of pain. The hallmark of palliative care is the concept of interdisciplinary collaboration. Hospice has provided an example of successful implementation of the interdisciplinary team model. An interdisciplinary and collaborative approach to pain management and pain care involving physicians, nurses, psychologists, social workers, pharmacists, and chaplains among a number of other disciplines is considered best practice across all health care settings. Even in primary care settings, it is incumbent upon health care practitioners to maintain dialogues with members of the other professions and seek support and counsel when appropriate in the assessment and treatment of pain, and the promotion of health literacy among older adult patients about prevention and access to care.

Conclusion

In conclusion, GSA expresses its strong opposition to broad-based restrictions on opioids that would have a detrimental and disproportionate impact on older adults’ access to effective pain management. In light of the strong evidence base supporting comprehensive assessment of older adults’ unique needs for appropriate medical and palliative interventions, and pain and symptom management, GSA favors a public health approach to the issue of non-medical use of prescription opioids that is fully integrated into health and social systems at all levels of society, identification of the multiple vectors and social contexts in which drug diversion, abuse and misuse occur, and substantial investments in training and education for all health care practitioners and members of the public.

Sincerely,

James C. Appleby, RPh, MPH
Executive Director & CEO
References


Griffin, Harmon & Kennedy (2012). Do patients with chronic low back pain have an altered level and/or pattern of physical activity compared to healthy individuals? A systematic review of the literature. Physiotherapy, 93(1); 13-23.


