



January 12, 2016

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Director
Centers for Disease Control and Prevention
1600 Clifton Road NE
Atlanta, GA 30329

Debra Houry, MD, MPH
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1600 Clifton Road NE
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RE: Docket Number CDC-2015-0112-CDC Draft Guideline for Prescribing Opioids for Chronic Pain; 2016

Dear Dr. Frieden and Dr. Houry,

The [Alliance for Aging Research](http://www.agingresearch.org) is the leading non-profit organization dedicated to accelerating the pace of scientific discoveries and their application to improve the experience of aging. The Alliance believes that advances in research help people live longer, happier, more productive lives and reduce health care costs over the long term and that access to the latest scientific information empowers people to take control of their health. The Alliance strives to advance science and enhance lives through a variety of activities and initiatives—from policy issues to provider and consumer health programs—that generate knowledge and action on age-related issues.

The Alliance has worked for a number of years on persistent pain and pain management issues among older adults. In 2009, we developed the patient brochure [Aging with Ease: A Positive Approach to Pain Management](#); in 2013 we released [The Silver Book: Persistent Pain](#), which spotlights the mounting burden of pain among older Americans, and the promise of innovation in mitigating that burden; and in [2009](#) and [2014](#) the Alliance released survey results on pain and over-the-counter pain management. We appreciate the opportunity to comment on the 2016 [draft Centers for Disease Control and Prevention Guideline for Prescribing Opioids for Chronic Pain](#) and we respectfully request modifications to this draft guideline in order for healthcare providers to deliver appropriate care to aging pain sufferers.

The burden of persistent pain for older adults is significant

Nearly 100 million Americans live with persistent pain.ⁱ More Americans are affected by pain than by diabetes, heart disease, and cancer combined.ⁱⁱ The incidence of persistent pain increases with age. Approximately 50 percent of non-institutionalized older adults suffer from persistent pain.ⁱⁱⁱ Between 62 percent and 83 percent of institutionalized elderly in the U.S. report a pain problem and 17 percent have substantial daily pain.^{iv} Pain in older adults can be attributed to factors such as surgery, invasive cancer, post-herpetic neuralgia, arthritis pain, back pain, among others. Such pain often results in more visits to healthcare professionals, increased hospital stays, disability, interference with activities of daily living, sleep disturbances, depression, thoughts of and attempts at suicide.

Older patients with persistent pain are too often undertreated or do not receive the appropriate therapy. Psychosocial factors, like the tendency of older adults to underreport their pain and the lower adherence rates to prescribed pain medications, complicate pain assessment and treatment.

Additionally, prescribing treatment can be complicated since opioids in older adults increase fall risk and confusion and can produce other negative side effects. Treatment is often further complicated by the fact that opioid medications, while highly effective for many patients, do carry the risk of addiction and therefore must be managed in a manner best suited for the individual.

We understand that increasing rates of opioid abuse and overdose in the United States have prompted federal actions aimed at limiting the prescription of opioid pain medication. However, we feel that the current CDC draft guideline will have the unintended effect of impeding opioid prescription access to the millions of legitimate pain patients who rely on this class of medications for daily function and/or to relieve suffering and restore quality of life. Our challenges with the current draft guideline may be attributed to the speed of the guideline development process, the lack of a transparent process, and the lack of balanced representation of pain experts on the committee responsible for the evidence review. We are pleased that CDC recently announced an additional working group of its Board of Scientific Advisors to review the draft guideline that includes such experts. It is also commendable that you issued a second call for public comments on the draft guideline to allow more transparency into the process. The Alliance for Aging Research has several recommendations on the draft that we hope you will consider in the final comment period to strengthen this guideline.

Better tailoring long-term opioid use

The introductory rationale contained on page 2 paragraph 4 of the draft guideline cites that primary care providers find managing patients with chronic pain stressful, that they express concern about patient addiction and report insufficient training in prescribing opioids. The rationale further states that while opioid pain medication can be effective in controlling pain, providers agree that physical dependence, tolerance and addiction are common consequences of prolonged use. Providers also report that long-term opioid therapy is often overprescribed for patients with chronic non-cancer pain.

The Alliance believes that the attitudes and views of healthcare providers are important to consider in developing prescribing guidelines but what is missing from this rationale is an acknowledgement that there is a limited evidence base for identifying chronic pain patients for whom long-term opioid treatment will be most effective, those individuals who are physiologically at higher risk of physical dependence on opioids, and those people who will experience reduced tolerance while on long-term opioid treatment. **We request the addition of a statement in this guideline that calls for the investment of federal resources in clinical research to assist providers in better tailoring long-term opioid use. We also request that HHS require a periodic review of the CDC guidelines and that an updated clinical evidence review of new research should accompany it.**

Non-pharmacologic and non-opioid treatment

Recommendation 1 in the draft guideline for determining when to initiate or continue the use of opioids relates to the use of non-pharmacologic therapy and non-opioid pharmacologic therapy as a first-line treatment of chronic pain. The recommendation states that opioids should only be added if the expected

benefits for both pain and function outweigh the risks to the patient. We agree that alternatives to opioids should be contemplated by patients and providers, but we feel that the guideline must consider the impacts of an evolving evidence base, the risks and benefits posed by any treatment, and current payment policies on the feasibility of implementing this recommendation.

First, we are concerned by the potential for the overuse of acetaminophen and non-steroidal anti-inflammatories (NSAIDs) by older adults for chronic pain management and that the risks associated with their use may be underestimated by providers attempting to avoid the prescription of an opioid. We think that the benefits and risks of these treatments must also be weighed by patients and providers, in addition to the risks and benefits of opioid treatment, particularly for older adults who have multiple chronic conditions. NSAIDs can be contraindicated for treatment because of many diseases concurrently experienced by seniors. Acetaminophen also has a maximum daily limit that can be exceeded in the pursuit of chronic pain management without proper education. In order to better inform patients and providers on the safe use of these products the Alliance for Aging Research will release a series of brief pocket films online, in the coming month. These films would be available for use by the CDC for educational purposes.

We applaud CDC for recognizing that many pain sufferers are able to find some relief through the use of non-pharmacologic interventions. These interventions include approaches such as acupuncture and manual manipulation. Other non-pharmacological interventions cited in the draft guideline include cognitive behavioral therapy and exercise therapy. While we support a range of treatments for pain management, we take issue with the studies included in the evidence review for this recommendation because they only demonstrate short-term benefit. The primary focus of this guideline is on the long-term management of chronic pain, so we feel that further evidence on non-pharmacologic approaches is needed before they can be suggested as an alternative to opioids. In addition, the ability of patients to initiate and continue these treatments over the long term is heavily dependent on coverage by health insurers. Most non-pharmacological treatments for pain are not reimbursed by public and private insurers. In the absence of a policy change, providers must consider a patient's financial and healthcare coverage status before prescribing a non-pharmacologic intervention as first-line treatment for chronic pain.

We ask that CDC expand Recommendation 1 to include a call on public and private payers to broadly cover the cost of non-pharmacologic interventions for pain sufferers. We believe that CDC should also request further research on the long-term benefits of complementary and alternative therapies for chronic pain management. Lastly, we request that CDC add more resources to www.cdc.gov on the safe use of non-opioid pain treatments, including those developed by stakeholders like the Alliance for Aging Research.

CDC dosage recommendations versus FDA-approved labeling

Recommendation 5 of the draft guideline suggests that providers should “implement additional cautions” when increasing dosing of opioids to >50 MME/day (morphine milligram equivalent) and to “avoid increasing dosages” to >90 MME/day. This recommendation falls in direct conflict with FDA-approved product labeling, which does not include dosage thresholds based on evidence review. Additionally, a June 2015 piece in the journal *Pain Medicine* found that “The lack of dosage uniformity and regulatory approaches across the United States raises the concern that dosage levels are not

informed by high-quality evidence, are arbitrary, and may amount to experimentation with increased risk to patients.” Comments submitted to you on October 1, 2015 by the American Medical Association (AMA) raised concerns about this recommendation and stated that “The reliance on expert opinion throughout this section, the existing multitude of state MME thresholds, and the absence of MME thresholds from the current product labeling for opioid analgesics coupled with a high degree of variability in patient responsiveness to opioids and uncertainty in morphine equivalent calculators, argue against establishing a bright line for clinical-decision making based solely on this variable.”

Recommendation 5 is not supported by existing evidence. We urge that this recommendation be removed from the list entirely.

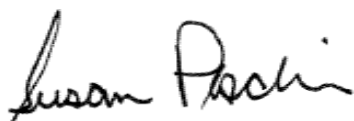
Acute Pain and Opioid Use

Recommendation 6 of the draft guideline attempts to limit opioid overuse as a result of short term treatment of acute pain. Comments submitted to you by the AMA raised concerns about a three-day limit imposed by the draft guideline for prescription of opioids to treat acute pain. The AMA highlighted that the clinical evidence provided in the evidence review for this recommendation focused largely on the emergency setting and that there is a lack of evidence to support this recommendation for use in treatment of acute pain post-surgery. We agree that this is an important area to focus attention on since prescription pain medication is commonly provided for acute pain after surgery and adults over age 65 are 2.6 times more likely to have surgery than those ages 45-64.^v After reviewing the draft guideline and the AMA comments we agree that the three-day limit is arbitrary.

We urge the modification of Recommendation 6 to remove a time or specific pill limit for acute pain treatment. The emphasis of this recommendation should be on healthcare providers prescribing the lowest dose of a short-acting opioid in a number and duration that the provider determines to be clinically necessary.

Thank you for your careful consideration of our views. Guidelines from the Centers for Disease Control and Prevention significantly impact decision making by healthcare professionals, public health officials, and patients. This specific guideline has the potential to negatively influence pain treatment, and persistent pain is a condition that already exacts a substantial burden on older adults. Opioids may not be the panacea, but they have helped reduce pain and improve function for millions of people. Future efforts and reforms should continue to focus on balance and the need to ensure access while preventing harm, rather than advocating for only one solution to a very complex problem. We hope to see our suggested revisions incorporated into the final guideline. If you have any questions or require additional information we can be reached by phone at (202) 293-2856 or by email cbens@agingresearch.org and speschin@agingresearch.org.

Sincerely,



Susan Peschin, MHS
President and CEO



Cynthia Bens
Vice President, Public Policy

ⁱ Institute of Medicine; Committee on Advancing Pain Research, Care and Education. *Relieving Pain in America: A blueprint for transforming prevention, care, education, and research*. Washington, DC: National Academies Press; 2011. <http://www.iom.edu/Reports/2011/Relieving-Pain-in-America-A-Blueprint-for-Transforming-Prevention-Care-Education-Research.aspx> Accessed: January 8, 2016

ⁱⁱ Tsang A, von Korff M, Lee S, et al. Common Chronic Pain Conditions in Developed and Developing Countries: Gender and age differences and comorbidity with depression-anxiety disorders. *J Pain*. 2008; 9(10): 883-91. <http://www.sciencedirect.com/science/article/pii/S1526590008005750> Accessed: January 8, 2016

ⁱⁱⁱ Thomas E. *Pain in Older People*. In *Chronic Pain Epidemiology: From aetiology to public health*, edited by Peter Croft, Fiona M Blyth, and Danielle van der Windt. New York, NY: Oxford University Press; 2010. http://fds.oup.com/www.oup.com/pdf/13/9780199235766_chapter1.pdf Accessed: January 8, 2016

^{iv} Ferrell B, Ferrell B, Rivera L. Pain in Cognitively Impaired Nursing Home Patients. *J Pain & Symptom Manage*. 1995; 10(8): 591-8. [http://www.jpmsjournal.com/article/0885-3924\(95\)00121-2/abstract](http://www.jpmsjournal.com/article/0885-3924(95)00121-2/abstract) Accessed: January 8, 2016

^v Hall M, DeFrances C, Williams S, Golosinskiy A, Schwartzman A. National Hospital Discharge Survey: 2007 Summary. *National Health Statistics Reports*. 2010; 29. <http://www.cdc.gov/nchs/data/nhsr/nhsr029.pdf> Accessed: January 9, 2016