



April 1, 2019

Alicia Richmond Scott
Pain Management Best Practices Inter-Agency Task Force
Office of the Assistant Secretary for Health
U.S. Department of Health and Human Services
200 Independence Avenue, SW, Room 736E
Washington, DC 20201

RE: Docket No. HHS-OS-2018-0027-0001

Dear Ms. Scott:

The undersigned members of the Protecting Access to Pain Relief (PAPR) Coalition wish to submit written comments in response to the notice entitled “Request for Public Comments on the Pain Management Best Practices Inter-Agency Task Force Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations” (HHS-OS-2018-0027-0001). The PAPR Coalition is a multi-stakeholder group of 17 public health organizations whose mission is to support continued access to and choice of appropriate over-the-counter (OTC) pain relief as part of a patient’s comprehensive pain management plan, including for use as alternatives to opioids (www.paprcoalition.com). Collectively, our Coalition reaches millions of healthcare professionals, people living with pain, patients managing chronic disease, and concerned citizens with public health messages about the safe use of OTC pain relief. Our combined communications and engagement platforms have proven to be a powerful resource with the demonstrated capacity to educate and mobilize Americans on complex and timely public health issues.

Currently, chronic pain affects an estimated 50 million U.S. adults, and as many as 19.6 million of those adults experience high-impact chronic pain that interferes with daily life or work activities.¹ Because of its near ubiquity nationwide, pain presents a significant public health problem in the U.S. An Institute of Medicine report found that pain costs our society at least \$560-\$635 billion annually (equal to about \$2,000 per person) in lost wages and compensation for disability days.² In addition, the costs of care associated with chronic pain, which include diagnostic tests, physical therapy, medications, and medication management, can be extremely burdensome on both patients and the healthcare system as a whole. A 2015 study of a large U.S. health integrated delivery system indicated that treating chronic pain costs approximately

¹ Dahlhamer J. et al. Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults - United States, 2016. *Morbidity and Mortality Weekly Report (MMWR)*. 2018; 67(36):1001-1006.

² Institute of Medicine Report from the Committee on Advancing Pain Research, Care, and Education: *Relieving Pain in America, A Blueprint for Transforming Prevention, Care, Education and Research*. The National Academies Press, 2011.

\$32,000 per patient per year, with an annual average of nearly 19 outpatient visits and five imaging tests per patient.³

We agree with the statement by HHS Secretary Alex Azar and Assistant Secretary Adm. Brett Giroir that “[A]s we combat the opioid crisis, we cannot forget that pain is a real problem... We must do a better job of securing for them safe, effective options for managing pain.” Recent research has shown that non-opioid pharmacologic alternatives have been shown to be as, if not more, effective than opioids in treating chronic pain over time.⁴ The Coalition believes policy makers should take additional steps to educate health care providers and patients about the important role of OTC pain medication as part of a safe and responsible pain management plan.

OTC pain relief – including use of acetaminophen – is often a medically necessary and cost effective way for patients to manage pain. In addition to lower costs, for many patients, such as those suffering from osteoporosis and end stage renal disease, OTC pain relief represents the safest medically recommended means of alleviating pain. It is important for Americans to have access to and choice of the appropriate OTC pain relief to match their pain profile and comorbidities.

Moreover, while we know that there are numerous safe and effective pharmacologic – including OTC medicines – and non-pharmacologic pain relief options on the market and available to patients, the incorporation of these therapies into a comprehensive pain management policy is not universal. In fact, comprehensive training in the development and execution of pain management plans for patients is frequently left out of graduate medical education curricula and current practice.⁵ In large part, these issues stem from inconsistent and disparate federal guidelines for pain management despite a large body of evidence that can inform a series universal best practices within the U.S. health care system.

The PAPR Coalition looks forward to working with stakeholders to pursue specific policy principles, including:

- Improving public health outcomes by ensuring patients have access to and choice of appropriate OTC pain relief therapies chosen with their health care provider as part of a comprehensive pain management plan that addresses potential risks of addiction to opioids;
- Ensuring that the Food and Drug Administration (FDA) does not unnecessarily limit access to OTC acetaminophen in the United States, including the 120 million Americans that have a health condition for which non-steroidal anti-inflammatory drugs (NSAIDs) are contraindicated;

³ Park PW et al. Cost burden of chronic pain patients in a large integrated delivery system in the United States. *Pain Practice*. November 2016; 16(8):1001-1011.

⁴ Krebs EE et al. Effect opioid vs. nonopioid medications on pain-related function in patients with chronic back pain or hip or knee osteoarthritis pain: The SPACE randomized clinical trial. *Journal of the American Medical Association*. 2018; 319(9):872-882.

⁵ Mezei L and BB Murinson. Pain education in North American medical schools. *J Pain*. December 2011; 12(12):1199-1208.

- Incorporating the patient experience and patient preference information into the FDA’s decision-making regarding policies related to current and future OTC pain relief therapies.

The PAPR Coalition strongly supports efforts by federal policy makers, including the Pain Management Best Practices Inter-Agency Task Force, to ensure Americans have access to and choice of appropriate OTC pain relief and that providers help their patients develop pain management plans that address the potential for misuse and abuse associated with opioids and appropriate use of all therapy options. In general, the Coalition is supportive of the Task Force’s Draft Report on Pain Management Best Practices and appreciates the opportunity to comment on the report’s observations and recommendations.

Section 2.2: Pain Medication

As mentioned previously, a main prong of the Coalition’s mission is to educate Americans about the safe use of appropriate OTC pain relief, especially as an alternative to opioids. The Coalition supports the inclusion of additional background information on pharmacologic OTC pain relief options, such as acetaminophen and non-steroidal anti-inflammatory drugs (NSAIDs), in order to increase their safe use by the public.

NSAIDs

NSAIDs represent an important OTC, non-opioid pain relief option for certain types of chronic pain. For instance, NSAIDs have been shown to aid recovery after an acute muscle injury.⁶ However, NSAIDs have been shown to be contraindicated for several populations, including those with kidney-related disorders or transplants,⁷ and can exacerbate conditions such as heart failure,⁸ among others. The PAPR Coalition recognizes and supports resources to ensure patients remain safe while taking NSAIDs, such as those developed by the National Institutes of Diabetes and Digestive and Kidney Diseases (NIDDK) to educate patients about acute kidney injury.⁹

Acetaminophen

The PAPR Coalition was founded to ensure access to and choice of safe and effective OTC pain relief, including OTC acetaminophen, for all Americans, especially for those populations for which NSAIDs are contraindicated. As a case in point, multiple members of the PAPR Coalition are major patient and professional stakeholders within the kidney community working to advance HHS initiatives recently highlighted by Secretary Azar aimed at increasing the availability of donated organs, increasing transplantation as preferred therapy for patients suffering from End Stage Renal Disease and assuring long-term transplant survival. For kidney patients and other disease populations, NSAIDs are not an option. Therefore, we believe patients

⁶ Morelli KM et al. Effect of NSAIDs on recovery from acute skeletal muscle injury: A systematic review and meta-analysis. *American Journal of Sports Medicine*. January 2018; 46(1):224-233.

⁷ Zhang X et al. Non-steroidal anti-inflammatory drug induced acute kidney injury in the community dwelling general population and people with chronic kidney disease: systematic review and meta-analysis. *BMC Nephrology*. 1 Aug. 2017; 18:256

⁸ Curfman G. FDA strengthens warning that NSAIDs increase heart attack and stroke risk. *Harvard Health Blog*. 22 Aug. 2017. <https://www.health.harvard.edu/blog/fda-strengthens-warning-that-nsaids-increase-heart-attack-and-stroke-risk-201507138138>.

⁹ National Institute of Diabetes and Digestive and Kidney Diseases. Keeping Kidneys Safe: Smart Choices About Medicines. June 2018. <https://www.niddk.nih.gov/health-information/kidney-disease/keeping-kidneys-safe>.

need access to all legally marketed doses of acetaminophen. We appreciate the Task Force’s comments in the draft report indicating that dose-dependent liver toxicity is a risk associated with exceeding the maximum daily dose of acetaminophen. Through its membership, the Coalition is dedicated to ensuring that all Americans have materials and other guidelines to promote the safe use of these products. Further, the Coalition has worked with federal stakeholders, including FDA, to further ensure that unified guidelines and recommendations exist to assist patients with the treatment of their chronic pain.

In pursuit of this goal, the Coalition developed and submitted an application in 2017 under FDA’s Safe Use Initiative. By utilizing the expertise of its collective membership, the Coalition developed a proposal to test the impact of behavioral economics-based digital messaging campaigns to educate patients about the safe use of acetaminophen. In its response to the Coalition’s Safe Use Initiative application, the FDA indicated that “the prevalence of unintended acetaminophen overdose is very low; 200 per year [in the United States].” While a positive indicator that current educational tools, labeling, and other forms of public information are working to help protect patients from unintentional harm, the Coalition will continue to promote a diverse array of educational materials on this issue.

- *Recommendation 1c:* In general, the lack of formal education for providers around pain management frequently results in the need for multiple healthcare professionals to be involved in designing such plans in accordance with a specific patient’s needs. Research has shown that the creation and utilization of interdisciplinary pain medicine teams is both cost beneficial and beneficial to the treatment of the patient.¹⁰ The PAPER Coalition supports the strong collaboration between the referring healthcare provider, the pain medicine team, and the patient to support adherence and effectiveness of pain management protocols utilizing OTC and nonpharmacologic pain relief options.
- *Recommendation 2a:* As mentioned previously, the PAPER Coalition strongly supports the recommendation that pharmacologic and nonpharmacologic pain relief options, including and especially OTC analgesics, be utilized as first-line therapy for both inpatient and outpatient settings. The Coalition further emphasizes the need for additional education for providers and patients concerning the safe use of any OTC analgesics for the treatment of pain, including any contraindications or hazards associated with preexisting medical conditions.
- *Recommendation 3c:* The PAPER Coalition is strongly supportive of the use of OTC analgesics, such as NSAIDs and acetaminophen, as first-line classes of medications for the treatment of nonneuropathic, noncancer pain. In 2016, the Centers for Disease Control and Prevention updated its guidelines to indicate that opioids should no longer be considered the first-line treatment option for noncancer pain.¹¹ Recent research from multiple national organizations has also indicated the increased adoption of multimodal pain management regimens that utilize OTC analgesics due to their positive balance

¹⁰ Gatchel RJ et al. Interdisciplinary chronic pain management: Past, present, and future. *American Psychology*. Feb. – March 2014; 69(2):119-130.

¹¹ Dowell D et al. CDC Guidelines for Prescribing Opioids for Chronic Pain – United States, 2016. *Morbidity and Mortality Weekly Report (MMWR)*. 18 March 2016; 65(1):1-49.

between patient safety and efficacy.¹² Finally, studies have indicated that opioids are no more effective for improving long-term, pain-related functions. For instance, one study determined that treatment with opioids was not superior to treatment with OTC analgesics for moderate to severe chronic back pain or hip/knee osteoarthritis pain.¹³

- *Gap 5:* The PAPR Coalition is concerned about the lack of public education around the safe disposal of excess opioids or other medicines. In addition to existing Task Force recommendations, the Coalition urges HHS to publish educational resources about the safe storage and disposal of all pain medicines, both opioid and nonopioid. Examples of existing resources related to this gap include the “Up & Away”¹⁴ to keep medications out of reach of children and resources developed and disseminated by Allied Against Opioid Abuse for the disposal of unused opioids.¹⁵ The Coalition stands by as a resource to assist with these efforts.

Section 2.3: Restorative Therapies

The PAPR Coalition’s mission includes ensuring access to safe OTC pain relief options, especially as alternatives to opioids. This includes utilizing nonpharmacologic options where applicable, including physical therapy, massage therapy, and other interventions. The PAPR Coalition strongly supports access to nonpharmacologic pain management resources as safe and effective pain management options to be used alone or in combination with OTC pain relief options like NSAIDs or acetaminophen.

Section 2.5.2: Chronic Pain Patients With Mental Health and Substance Use Comorbidities

- *Recommendation 1d:* The PAPR Coalition is supportive of the use of non-opioid alternatives as safe and effective options for those with a history of opioid use disorder, either alone or in conjunction with the lowest effective dose. Pain management training should include specific information for providers about the development of pain management plans for these patients that utilize pharmacologic and nonpharmacologic OTC pain management options for those with opioid use disorder.

Section 2.7: Specific Populations

Section 2.7.1: Unique Issues Related to Pediatric Pain Management

- The PAPR Coalition supports the use of OTC analgesics for the treatment of chronic pain in the pediatric population, especially as a pain relief alternative for the 3.1 percent of youth ages 12 to 17 and 7.3 percent of adolescents ages 18 to 25 that reported misusing

¹² Nalamachu S. et al. Over-the-counter analgesics for the management of acute pain: Clinical experience in the era of the opioid crisis. *Pain Management News* (supplement). January 2019.

https://www.painmedicineneeds.com/download/SR194_WM.pdf.

¹³ Krebs EE et al. Effect opioid vs. nonopioid medications on pain-related function in patients with chronic back pain or hip or knee osteoarthritis pain: The SPACE randomized clinical trial. *Journal of the American Medical Association*. 2018; 319(9):872-882.

¹⁴ <https://www.upandaway.org/>.

¹⁵ <https://againstopioidabuse.org/resource/safe-disposal/>.

opioids.¹⁶ Given the propensity for behaviors developed in childhood to continue into adulthood, non-addictive pain relief options, such as OTC analgesics, represent safe and effective alternatives to help prevent future opioid misuse. Further, the Coalition urges parents and caretakers to carefully follow the advice of their provider in providing OTC medicines to children and to follow any evidence-based and scientifically valid weight-based dosing information for these populations. The Coalition is currently working with policymakers to ensure that weight-based dosing information for children ages six months to two years is applied to acetaminophen labeling to promote safe administration of these products to children.

Section 2.7.2: Older Adults

- The PAPER Coalition strongly supports the use of a multidisciplinary approach that utilizes non-opioid alternatives such as OTC analgesics in the aged population. The use of non-opioid alternatives in this population expands access and lowers barriers to safe and effective pain relief by potentially reducing office visits in between regular and necessary evaluations. Further, the use of non-opioid alternatives is crucial for this population, which is frequently more susceptible to both respiratory depression and reduced medication clearance related to decreased renal function.¹⁷ Finally, educational materials should be tailored to this population to enhance the safe use of OTC pain relief options.

Section 2.7.3: Unique Issues Related to Pain Management in Women

- *Recommendation 2a:* The PAPER Coalition strongly supports inclusion of obstetricians and gynecologists as part of multidisciplinary care. The Coalition recommends that specific education around pain management for women utilizing non-opioid OTC alternative pain relief options, as appropriate, be included in graduate medical education curricula nationwide. This is especially true given that chronic and high-impact chronic pain have a higher prevalence among women.¹⁸

Section 3.2: Public Education

Section 3.2.2: Patient Education

- *Recommendations 1a/3a/3b:* One of the main tenets of the PAPER Coalition’s mission is to educate patients about the safe use of OTC pain relief options, especially as an alternative to opioids. Collectively, the Coalition is able to reach and disseminate

¹⁶ Substance Abuse and Mental Health Services Administration (SAMHSA) (2017) Key substance use and mental health indicators in the United States: Results from the 2016 National Survey on Drug Use and Health (HHS Publication No. SMA 17-5044, NSDUH Series H-52) Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from <https://www.samhsa.gov/data/>.

¹⁷ Wu A. Special consideration for opioid use in elderly patients with chronic pain. *U.S. Pharmacist*. 16 March 2018; 43(3):26-30.

¹⁸ Dahlhamer J. et al. Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults - United States, 2016. *Morbidity and Mortality Weekly Report (MMWR)*. 2018; 67(36):1001-1006.

educational materials to millions of patients, their families, caregivers, and health care providers. The Coalition will continue to serve as a resource for patients suffering from chronic pain, and encourages the Pain Management Best Practices Inter-Agency Task Force to work collaboratively with the Coalition, its members, and other external stakeholders to cross-promote, develop, and disseminate educational materials for the benefit of patients across the nation. In addition, the Coalition's members have strong relationships with scientific experts, patients, and advocates that can be useful for the creation of expert panels related to pain management and education.

Section 3.2.3: Provider Education

- *Recommendation 1b/1c:* The PAPER Coalition supports expanding residency positions to increase awareness of pain management amongst healthcare profession students as well as supporting the expansion of nonphysician specialist to treat chronic pain issues. Educational opportunities, to include specific residency programs, internships, and other resources, should be extended beyond the physician space to other types of providers, such as nurse practitioners, physician assistants, and pharmacists, who are intimately involved with care coordination, and treatment determination, for patients with pain management needs.

As mentioned previously, pain management education is rarely included in graduate medical education curricula in the United States. Although there was early success in the 1970s and 1980s in providing multidisciplinary pain management resources for those with chronic pain, resource and economic factors (i.e. reimbursement), the pursuit of pain management as an individual, rather than team-focused, subspecialty, and the incorporation of incomplete and misleading information related to opioid addiction into graduate medical education resulted in a reliance on opioids as a treatment for chronic pain.¹⁹ Unfortunately, this trend has not reversed itself, further exacerbating the opioid crisis. A 2009/2010 physician survey conducted by the Association of American Medical Colleges indicated that of 104 medical schools evaluated, only four offered a required course on pain, with other studies finding that many medical schools required only five or fewer hours of training in pain treatment.²⁰

Certain medical schools, such as the University of Washington, have successfully integrated pain management training into their curricula, resulting in a quadrupling of required pain education teaching time.²¹ These types of improvements should become the standard in graduate medical education, and accrediting bodies should factor this training into their requirements for medical schools in the United States.

¹⁹ Tompkins DA et al. Providing chronic pain management in the “fifth vital sign” era: Historical and treatment perspectives on a modern-day medical dilemma. *Drug and Alcohol Dependence*. 1 April 2017; 173(Supp. 1):S11-S21.

²⁰ Mezei L and BB Murinson. Pain education in North American medical schools. *J Pain*. December 2011. 12(12):1199-1208.

²¹ Tauben DJ and JD Loeser. Pain education at the University of Washington School of Medicine. *J Pain*. May 2013; 14(5):431-437.

In addition, the PAPR Coalition recommends that clinical indications and effective use of OTC analgesics as part of a multimodal and multidisciplinary approach to acute and chronic pain management should be a critical piece of graduate medical education in the United States.

Finally, the Coalition recommends further research into the categorization of post-recovery chronic pain as a category of disease. Arguments have been made that such a categorization would raise awareness of the issue of chronic pain management²² and may lead to additional provider training and increased access to treatment within the U.S. healthcare community.

Section 3.3: Access to Care

3.3.2: Insurance Coverage for Complex Management Situations

- In general, the PAPR Coalition is supportive of payment schemes that increase access to safe and effective pain management alternatives, especially structures that promote equity for coverage of nonopioid alternatives to pain relief for the patients that need them. This includes coverage options that maximize the ability of physicians and non-physicians providers, such as nurse practitioners, physician assistants, pharmacists, etc., to provide comprehensive pain management to the patients that need them and for out-of-pocket expense for the patient to be negligible or free.

Section 3.3.4: Research

- *Recommendation 1a:* The PAPR Coalition strongly supports clinical research into chronic pain and its treatment, especially using non-opioid alternatives. The Coalition encourages the federal government to coordinate efforts around this through NIH's Interagency Pain Research Coordinating Committee and to consult all NIH Institutes and Centers to understand how chronic pain treatment may interact with patients with special health care needs, such as the transplant and transplant-eligible communities. The Coalition further encourages federal coordination of pain management policy at the Department of Health and Human Services level, with other agencies actively contributing to an overall research agenda that prioritizes research and training around new modes and methods of chronic pain treatment and management.

The PAPR Coalition, with our substantial combined audience and communications and engagement capacities, is dedicated to working with the HHS Pain Management Best Practices Inter-Agency Task Force, Congress, and other allied stakeholders to help support the millions of Americans living in persistent pain with access to and choice of appropriate OTC pain relief within tailored pain management plans for the millions of Americans who suffer from chronic pain. We view the work of the Task Force to be crucial in ensuring that Americans have complete information about safe and effective options to treat their pain and urge that a task force of this nature continues in the future.

²² Raffaelli W. and E. Arnaudo. Pain as a disease: An overview. *Journal of Pain Research*. 2017; 10:2003-2008.

If you have any further questions about the Coalition, please email Paul Conway (paulconway@cox.net) or Patricia D'Antonio (pdantonio@geron.org).

Sincerely,

Alliance for Aging Research
American Association of Kidney Patients
American Gastroenterological Association
American Pharmacists Association
American Society of Nephrology
BeMedWise Program at NeedyMeds
The Gerontological Society of America
National Minority Quality Forum
Renal Physicians Association
TransplantFirst Academy
U.S. Pain Foundation
Veterans Transplantation Association