



**Testimony
From The
Protecting Access to Pain Relief (PAPR) Coalition
House Committee on Energy and Commerce
October 25, 2017**

The Protecting Access to Pain Relief (PAPR) Coalition is pleased to submit this testimony in response to the House Energy and Commerce Subcommittee on Health’s hearing entitled “Federal Efforts to Combat the Opioid Crisis: A Status Updated on CARA and Other Initiatives.”

The PAPR Coalition is a multi-stakeholder group of 16 public health organizations able to collectively reach out to millions of medical professionals, people living with pain, patients managing chronic disease, and concerned citizens whose mission is to advocate for public policy that supports continued access to and choice of appropriate over-the-counter (OTC) pain relief. Our list of members and other information can be found at our website www.paprcoalition.com. The PAPR Coalition remains dedicated to ensuring patients’ access to the OTC pain relief they need as a part of their care regimen while continuing its efforts to educate the public about the appropriate use of acetaminophen and ensure patient safety by promoting the use of non-opioid pain relief options.

Currently, over 100 million Americans suffer from chronic pain; that is more than the number of patients suffering from diabetes, stroke, coronary artery disease and cancer combined.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

¹ AAPM Facts and Figures on Pain. *The American Academy of Pain Medicine*. http://www.painmed.org/patientcenter/facts_on_pain.aspx#refer.

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.

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 found that treating chronic pain costs approximately \$32,000 per patient per year, with an annual average of nearly 19 outpatient visits and five imaging tests per patient.³

Within these overall expenditures, the total cost of medication prescribed for pain is enormous, with one study indicating \$17.8 billion in total annual spending on prescription medication for pain that includes analgesics, nonsteroidal inflammatory drugs (NSAIDs), opioids, muscle relaxants, and topical products.⁴ Further, over a seven-year period the number of outpatient visits made for chronic pain increased by three percentage points, indicating that diagnoses of chronic pain requiring some form of medication-based treatment will likely continue to increase over time.⁵

OTC pain medication, specifically acetaminophen, is often a medically necessary and cost effective way for patients to manage pain. There are approximately 120 million adults in the U.S. have a health condition for which NSAIDs and certain other pain medications are contraindicated. These patients rely on acetaminophen for pain relief.

Therefore, in addition to lower costs, for many patients, OTC pain relief, and specifically acetaminophen, represents the safest medically recommended means of alleviating pain caused by illnesses and co-morbidities ranging from osteoporosis to end-stage renal disease. Moreover, access to non-opioid therapies for pain are more important than ever. The opioid epidemic is still flourishing nationwide. Opioid overdose alone led to the death of more than 500,000 people in the U.S. from 2000 through 2015, and in 2014 alone almost 2 million Americans abused or were dependent on opioids for pain relief.⁶ Increased availability of these potentially harmful medications has fueled this epidemic. Nearly 250 million prescriptions for

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 Rasu RS et al. Cost of pain medication to treat adult patients with nonmalignant chronic pain in the United States. *Journal of Managed Care & Specialty Pharmacy*. September 2014. 20(9):921-928.

⁵ Ibid.

⁶ “Opioid Overdose: Understanding the Epidemic.” Centers for Disease Control and Prevention (CDC). 30 Aug. 2017. <https://www.cdc.gov/drugoverdose/epidemic/index.html>.

opioid medication were written in 2014 alone, with significant differences in the numbers of prescriptions written across geographic areas and states that make public health responses to these issues difficult.⁷ Thus, in the U.S., addictive opioid medications have become the *de facto* first-line treatment for chronic pain rather than a possible secondary option carefully considered by a patient and his or her healthcare team.

The opioid crisis provides another reason for policy makers to ensure that patients have full access to all appropriate doses of OTC acetaminophen. While any medication is only a part of the total balanced approach to pain management, the Coalition believes that any attempt to curtail access to these safe and effective pain relief options would be a detriment to the vast number of patients whose chronic pain may be effectively managed through OTC and other non-opioid medications. In addition, the Coalition believes policy makers should take additional steps to educate prescribers, other health providers, and professionals and patients about the value of OTC pain medication while ensuring these products are used safely.

The PAPR Coalition strongly supports efforts by Congress to empower federal agencies, such as the FDA, the NIH, the CDC, and the Office of National Drug Control Policy (ONDCP), to responsibly and constructively address not only access to important OTC pain relief therapies but also promote provider and patient education to ensure that patients are using safe and effective pain relief while avoiding the strong potential for misuse and abuse associated with opioids. More specifically, the PAPR Coalition looks forward to working with policy makers and external stakeholders to pursue specific policy objectives including:

- Improving public health by ensuring patients have full access to OTC pain relief therapies, including maximum strength acetaminophen;
- Partnering with external stakeholders, including the FDA and NIH, to ensure the safe use of pain medications, including OTC pain medications, through patient and provider education and other informational activities;

⁷ “Opioid Overdose: Prescription Opioids.” Centers for Disease Control and Prevention (CDC). 30 Aug. 2017. <https://www.cdc.gov/drugoverdose/opioids/prescribed.html>.

- Promoting the use of non-pharmacologic and non-addictive pharmacologic pain relief options, including OTC pain relief, to ensure patients are not harmed through dependency on opioid and other potentially addictive pain relief options;
- 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.

As new efforts are being developed to combat the opioid crisis while increasing patient health and quality of life, the PAPR Coalition is dedicated to working with other interested stakeholders and Congress to help educate patients and their physicians about the need for access to safe and dependable treatment options for the millions of Americans who suffer from chronic pain.

If you have any further questions about the Coalition, please email Michael Werner (michael.werner@hklaw.com) or Joel Roberson (joel.roberson@hklaw.com).