

November 1, 2019

Lauren Zeise, PhD
Acting Director
California Office of Environmental Health Hazard Assessment
1001 I Street
Sacramento, CA 95814

Re: Proposition 65 warning and potential negative effects on appropriate pain management

Dear Dr. Zeise:

The undersigned members of the Protecting Access to Pain Relief (PAPR) Coalition wish to express concern with potential actions by the California Office of Environmental Health Hazard Assessment (OEHHA) that would list acetaminophen as a carcinogen under The Safe Drink Water and Toxic Enforcement Act of 1986, also known as Proposition 65.

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.

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. For millions of patients, acetaminophen represents the only OTC pain relief option available, as other alternatives such as non-steroidal anti-inflammatory drugs (NSAIDs) and opioid medications carry risk of adverse health reactions for these populations. Thus, it is important for Americans to have access to and choice of the appropriate OTC pain relief to match their pain profile and comorbidities.

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.

The PAPR Coalition is concerned that listing acetaminophen as a carcinogen under Proposition 65 without extensive scientific evidence supporting the claim may dissuade consumers from choosing the OTC pain relief options deemed most appropriate for their condition by their physician. This is especially true given recent research indicating no evidence of increased risk of carcinogenicity linked to acetaminophen use for a large majority of cancer types.³ Preclinical studies have also indicated no meaningful link between acetaminophen and cancer.⁴ The PAPR Coalition strongly urges that the OEHHA adequately balance the risks of taking acetaminophen with the benefits of acetaminophen as a safe and effective OTC pain medication when making its carcinogenicity determination, and that such a determination be based upon the strongest science.

We thank you for your attention to this important issue. Should you have any questions, please contact Michael Werner (michael.werner@hklaw.com) or Joel Roberson (joel.roberson@hklaw.com).

Sincerely,

Alliance for Aging Research
American Association of Kidney Patients
American Chronic Pain Association
American Gastroenterological Association
The Gerontological Society of America
National Minority Quality Forum
Renal Physicians Association
TransplantFirst Academy
Veterans Transplantation Association

³ Weiss NS. Use of acetaminophen in relation to the occurrence of cancer: a review of epidemiologic studies. *Cancer Causes Control*. 2016;27(12):1411-1418.

⁴ International Agency for Research on Cancer (IARC) - Summaries & Evaluations Volume: 73 (1999) (p. 401).