



October 25, 2019

Tyler Saechao  
Office of Environmental Health Hazard Assessment  
P.O. Box 4010, MS-12B  
Sacramento, California 95812-4010

Dear OEHHA and CIC Members:

The California Rheumatology Alliance (CRA) is writing to share our concerns regarding the upcoming Proposition 65 review of acetaminophen by the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment's (OEHHA) Carcinogen Identification Committee (CIC).

**CRA strongly urges the CIC not to "list" acetaminophen as a carcinogen due to the lack of evidence that it has been "clearly shown" to cause cancer and due to the unnecessary confusion and fear it could cause among consumers and patients.**

Acetaminophen is one of the most commonly-used prescription and over-the-counter (OTC) drug ingredients in the U.S. – and one on which Californians have long depended for safe and effective temporary relief of pain, fever, or minor aches. Its benefits have been recognized by the U.S. Food and Drug Administration (FDA), by other health agencies globally, and it is widely recommended by rheumatologists especially for certain populations for whom other pain relievers, like NSAIDs, may not be appropriate. For patients with chronic diseases, acetaminophen is often the most appropriate option for pain relief. It also is an alternative for those patients who may not need stronger medications such as opioids.

In terms of the scientific evidence, acetaminophen is one of the most studied and trusted medicines available today, with more than 250 clinical studies and more than 50 years of real-world use. Extensive data generated through epidemiologic, genotoxicity, and animal carcinogenicity studies do not support a conclusion that there is a causal relationship between acetaminophen and cancer, and no health agency globally currently deems acetaminophen to be a carcinogen. OEHHA's stated criteria for listing a chemical under Prop 65 is that it "must be clearly shown through scientifically valid testing" to cause cancer, and the evidence for acetaminophen does not meet this standard.

The decision before the CIC is an important public health issue that is of enormous consequence: getting it wrong could create significant consumer confusion, unnecessary fear,

and potential harm. An unsubstantiated Prop 65 listing of acetaminophen and potential cancer warning on products containing acetaminophen could inappropriately frighten millions of consumers and drive patients to either other pain medication with a less favorable benefit-risk profile for their individual medical needs, to an unproven therapy, to less effective non-medical options, or perhaps even to not treating their pain at all.

Given the current pain management landscape in the U.S., it is counter productive to be unnecessarily frightening people away from using safe, effective, and trusted pain medications like acetaminophen.

As the committee proceeds with its review of acetaminophen, we strongly encourage the CIC to recognize that acetaminophen does not meet the “clearly shown” standard required for listing as a carcinogen, and that serious consideration be given to the important role acetaminophen plays in the lives of Californians every day.

Sincerely,

A handwritten signature in black ink, appearing to read "Samy Metyas", with a long horizontal flourish extending to the right.

Samy Metyas, MD  
President, California Rheumatology Alliance (CRA)