June 13, 2014

Monet Vela
Office of Environmental Health Hazard Assessment
P. O. Box 4010
1001 I Street
Sacramento, California 95812-4010

RE: P65 Warning Regulation

Ms. Vela:

The California Medical Association (CMA) appreciates the opportunity to comment on the proposed amendments to Title 27, California Code of Regulations, Article 6: Clear and Reasonable Warnings. CMA is a professional organization that represents more than 40,000 California physicians dedicated to the health of all Californians, and as such takes great interest in how Proposition 65 relates to prescription drugs and devices.

Prescription Drugs
We appreciate that CMA’s concerns expressed at the April 14 workshop were heard and that the Office of Environmental Health Hazard Assessment (OEHHA) has decided to not proceed with changes to informed consent as they relate to prescription drugs. As we have discussed, the proposed language would have mandated additional Proposition 65 disclosure as part of an informed consent process that takes place when a physician and patient decide a course of medical treatment.

Under current law, a physician is already required to disclose to a patient all information that is relevant to a meaningful decision-making process. This can include information on cancer and developmental toxicity, and the law appropriately leaves the definition of what is material to the prescriber based on the facts of each patient's individual circumstances. In addition, the federally-approved materials included with prescription drugs represent a scientific presentation of information. Prescription drugs, by nature of their Food and Drug Administration (FDA) approval, have established medical risks and benefits, which physicians consider each time they prescribe a particular treatment and, for those risks or benefits material to a particular patient's decision, each time they obtain informed consent from a patient. In contrast, standard signage and other generic forms of warning don’t include an assessment of risk, or any indication
of relative risk. A one-size fits all approach is not appropriate for the practice of medicine. A mandated discussion would confuse patients, reduce adherence, and potentially lead to refusal of potentially life-saving medications.

**Prescription Medical Devices**

CMA finds that the establishment of a safe harbor for prescription medical devices similar to that of prescription drugs makes sense, as they too are heavily regulated by the FDA with patient safety in mind. The risks and benefits associated with the use of FDA-approved prescription medical devices, many of which are used in medical procedures and treatments, also need to be considered on a patient by patient basis.

Despite similarities in the overall considerations applicable to prescription medications and prescription medical devices, CMA believes that the creation of a new section for prescription medical devices is warranted. Devices evaluated by the FDA can include a wide range of items, from a permanently implantable device such as a hip implant to syringes and catheters. While a prescriber will typically recommend a particular hip implant and could reasonably be expected to be able to obtain informed consent for use of the particular device prescribed, the same is not true for other items. For example, a prescriber does not typically have control over the various medical devices routinely used in invasive treatments or surgical or other procedures, because a facility, such as a hospital, provides those items as part of its services. In addition, for commonly used items or commonly known risks, simple consent and a different process of notification may be warranted. For these reasons, the burden of ensuring that the patient has appropriate information about all prescription medical devices should not be bourn entirely by prescribers.

Other differences also support the creation of a new section for prescription medical devices. The term "prescription medical devices" is broad and can be somewhat ambiguous given the wide range of classifications and restrictions that can be placed on various devices as part of the FDA’s product evaluation and approval process. Potential ambiguities that need clarification may materialize after the passage of time. Thus, while CMA does not suggest a definition in these comments, we do ask that a new section for prescription medical devices be established, which would provide for the opportunity to clarify definitions and procedures relating to devices in the future without also impacting the language related to prescription drugs.

CMA proposes the following language for a new section on prescription medical devices, which does not specify who needs to obtain consent and allows for both simple and informed consent based on current state law:
“For prescription medical devices, the labeling approved or otherwise provided under federal law and the practice of obtaining a patient's consent under state law shall be deemed to be a clear and reasonable warning.”

CMA welcomes the opportunity to work with OEHHA on language related to medical practice and patient consent. If you have any questions, feel free to contact me at sclark@cmanet.org or 916-551-2887. Thank you for your consideration.

Sincerely,

Scott Clark
Associate Director, Center for Medical & Regulatory Policy