June 5, 2014

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Re: P65 Warning Regulation

On behalf the California Healthcare Institute (CHI), the statewide public policy association representing the innovative life sciences sector – biotechnology, pharmaceutical, medical device and diagnostics companies, venture capital firms, research universities and institutes and its 267,000 workers – please accept these comments to the proposed amendments for prescription drugs and prescription medical devices under Title 27, California Code of Regulations, Article 6: Clear and Reasonable Warnings. We understand that OEHHA has decided to revert the proposed section 25607.5 to the existing language in section 25603.3, and to extend that exemption to medical devices. We strongly support that decision for the following reasons.

If implemented, the proposed changes would expose manufacturers to frivolous lawsuits, impose duplicative regulations on labeling, impose requirements that would conflict with federal law, delay access to medical treatment, confuse patients and deter the use of beneficial products.

Prescription drugs and medical devices are heavily regulated by the Federal Food and Drug Administration (FDA), which performs a sophisticated and thorough risk-utility analysis before drugs and devices are approved for the market. Using information derived from clinical trials, manufacturers work with the FDA to carefully balance warnings so as not to deter the use of beneficial products. Labels are reviewed by physicians who use their extensive training when prescribing a drug or device to weigh the risks while also achieving desired medical outcomes in consultation with their patients.

Requiring information beyond what is required by the FDA interferes with precisely crafted warnings that balance all relevant considerations. Additional warnings can confuse and mislead consumers, deterring them from using drugs or devices against the advice of medical professionals and conflict with federal law. This point was articulated in the 2004 California Supreme Court case Dowal v. Smithkline Beecham. Expressing the unanimous view of the court, Associate Justice Joyce L. Kennard opined that “the mere existence of a risk... is not necessarily enough to justify a warning; the risk of harm may be so remote that it is outweighed by the greater risk that a warning will scare consumers into foregoing use of a product that in most cases will be to their benefit.” The lawsuit surrounded an over-the-counter product, but the court’s ruling has even greater implications for serious health conditions that can only be treated by prescription drugs and medical devices. Overwarning patients with dire health conditions is counterproductive and dangerous, for instance, warning a cancer patient undergoing chemotherapy that chemotherapy can cause cancer.

As written in the Department’s “Initial Statement of Reasons,” it is true that references to carcinogens or reproductive toxicity are “implicit” in Federal regulations for prescription drugs: the FDA already requires such information to be disclosed (21 CDF 201.57(c)(14), “13 Nonclinical Toxicology”). However, cases may arise where information contained in FDA labeling could be interpreted as inconsistent or insufficient to “clearly communicate” Proposition 65 warnings. As an example, the defendants in Dowal v. Smithkline Beecham were sued because although the warning on their product contained information about the dangers to pregnant women as required by the FDA, the warning was not written exactly as required by Proposition 65. Additionally, inactive ingredients found in prescription drugs listed within Proposition 65 create even more legal vulnerabilities, even though risks from the presence of these chemicals has been taken into full consideration by the FDA. For prescription medical devices, information regarding carcinogens and reproductive toxicity is not “implicit” in FDA regulations, as they must comply with a different and unique set of regulations. Companies selling prescription medical devices in California already have effective compliance strategies to meet the requirements of Proposition 65, for example sending an annual letter to hospitals detailing Prop 65 chemicals contained in their products. Under the current proposal, all of these scenarios expose manufacturers to litigation.

The proposed language “except prohibited by Federal law” is practically meaningless as the FDA has no regulation specifically indicating that Proposition 65 warnings are “prohibited.” Rather, manufacturers must seek FDA approval to make any changes to labeling, and new or additional warnings must be ruled on by the FDA on a case-by-case basis. The dynamic changes in listings of Proposition 65 substances would create a situation of ever-changing labeling requiring formal FDA approval (in the alternative, Proposition 65 may not keep pace with changes in the FDA knowledge base). This California differentiation would result in unnecessary expenses for both manufacturers and the FDA and create delays for California patients seeking treatments that have already been through rigorous FDA approval procedures. Finally, in every instance where it is unclear if Proposition 65 requirements are “prohibited,” litigation would ensue to make that determination.

For these reasons, CHI strongly supports OEHHA’s decision to revert the proposed section 25607.5 to the existing language in section 25603.3, and to extend that exemption to medical devices. Doing so will serve the best interests of public health in California and give innovative companies certainty they are protected from frivolous lawsuits.

We look forward to working with the department to address these concerns. Please feel free to contact Eve Bukowski at bukowski@chi.org or 916-233-3497.

Sincerely,

Eve Bukowski
Vice President – State Government Affairs