

## LANDMARK RULING STRIKES DOWN APPLICATION OF CALIFORNIA'S PROPOSITION 65 CANCER WARNING



In the first declaratory judgment action ever tried under California's Proposition 65, a California trial court issued a landmark ruling on October 10 striking down the application of Proposition 65's cancer warning requirement to DEHP, a plasticizer used in nearly all medical devices. *Baxter Healthcare Corporation v. California*, No. 99CS00868\*. The court found that the chemical poses "no significant risk of cancer" to humans. It rejected experimental animal data as a basis for the state to regulate DEHP under Proposition 65. The decision offers medical device, pharmaceutical, oil and chemical, and cosmetic companies a new strategy for challenging the warning provisions of Proposition 65.

### BACKGROUND

In November 1986 California voters overwhelmingly approved Proposition 65, an initiative to address growing concerns about exposures to toxic chemicals. That initiative became The Safe Drinking Water and Toxic Enforcement Act of 1986. Proposition 65's unique requirements, extreme penalties and broad reach make it one of the most important and dynamic environmental and product labeling laws in existence today. It is one of the largest areas of litigation in California and poses a significant problem to a wide variety of manufacturers.

Proposition 65 requires the state of California to publish a list of chemicals "known to the state of California to cause cancer." Early in the history of Proposition 65, the state decided to include on the list even chemicals known only to cause cancer in experimental animals. Any company manufacturing, using or selling these chemicals within the state must warn the ultimate user that such chemical is "known to the State of California to cause cancer." In addition, employers using such chemicals in their manufacturing operations must so warn their employees. Manufacturers that release these chemicals into the environment, even accidentally, are obligated to warn all potentially exposed parties. Failure to provide the warning results in exceedingly heavy penalties.

The warning requirement does not apply if it can be demonstrated that the exposure to the chemical in question poses no significant risk of cancer to humans. According to the state’s interpretation, however, this exemption is purely a quantitative one: it applies only if exposure to the chemical does not exceed a state-promulgated “No Significant Risk Level.” Because this exemption requires a company to prove a negative, it has had limited value as a defense to an enforcement action by the state.

Baxter’s strategy was to take the offensive against the state of California. The company, which uses DEHP in its intravenous feeding tubes, cardiovascular devices and kidney dialysis equipment, sued the state for a declaratory judgment that DEHP poses no significant risk of cancer. Baxter contended that the lack of a significant risk could be demonstrated qualitatively. It argued that the mechanism by which DEHP causes cancer in rats and mice does not operate in humans, and that DEHP cannot, therefore, be deemed a human carcinogen.

Baxter began by establishing, for the first time, that the “no-significant-risk” defense can be raised through a declaratory judgment action, rather than solely as an affirmative defense to an enforcement action. This procedural victory fundamentally changed the nature of the trial. First, it gave Baxter the advantage of going to trial as a plaintiff, rather than as a defendant. Second, the evidentiary standard governing the trial became preponderance of the evidence, rather than the more typical clear and convincing or abuse of discretion standards.

After two weeks of testimony by leading experts in the fields of carcinogenesis, epidemiology, neonatology and hepatology, the court ruled for Baxter, stating: “DEHP is known to cause cancer only in rats and mice. The mechanism by which it does so does not operate in humans. No alternative mechanism by which it could do so has been sufficiently delineated or investigated so as to be anything other than speculation or unconfirmed hypothesis at this time.”

## HOW DOES THIS RULING AFFECT YOUR COMPANY?

With this ruling, California’s listing of DEHP as a chemical “known to the state of California to cause cancer” is effectively nullified. All manufacturers, sellers and users of DEHP have a complete defense to any Proposition 65 enforcement action brought by the state of California, citizens’ groups, counties or bounty hunters. In a broader sense, the ruling offers a whole new avenue of challenge to Proposition 65 listings that are based on animal data.

### CONTACT INFORMATION

If you have questions about this case, or would like to learn more about Proposition 65 and its implications for your company, please contact:

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