

CERTIFIED FOR PUBLICATION

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA  
THIRD APPELLATE DISTRICT  
(Sacramento)

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BAXTER HEALTHCARE CORPORATION,  
  
Plaintiff and Respondent,  
  
v.  
  
JOAN E. DENTON, as Director, etc.,  
et al.,  
  
Defendants and Appellants.

C043352  
  
(Super. Ct. No.  
99CS00868)

APPEAL from a judgment of the Superior Court of Sacramento County, Talmadge R. Jones, Judge. Affirmed.

Bill Lockyer, Attorney General, Richard M. Frank, Chief Assistant Attorney General, Theodora Berger, Senior Assistant Attorney General, Craig C. Thompson, Supervising Deputy Attorney General, Susan L. Durbin, Janill L. Richards and Edward G. Weil, Deputy Attorneys General, for Defendants and Appellants.

Adams Nye Sinunu Bruni Becht and Bruce Nye for Plaintiff and Respondent.

Under Proposition 65, a business must provide a warning when it exposes the public to a chemical that is on a list of chemicals

known to the state to cause cancer in animals. However, a warning is not required if the business can show that the exposure poses no significant risk of causing cancer in humans. (Health & Saf. Code, § 25249.5 et seq.; further section references are to the Health and Safety Code unless otherwise specified.)

Director Joan Denton and the Office of Environmental Health Hazard Assessment (collectively OEHHA), which is the lead agency charged with implementing Proposition 65, appeal from the superior court's judgment declaring that a chemical plasticizer contained in medical devices manufactured by Baxter Healthcare Corporation (Baxter) poses no significant risk of causing cancer in humans and, therefore, Baxter need not provide the warning of carcinogenicity required by Proposition 65.

OEHHA raises various procedural challenges to the superior court's ruling and also claims the decision is not supported by substantial evidence. We shall affirm the judgment.

As we will explain, Proposition 65 does not preclude a business from bringing a declaratory relief action under Code of Civil Procedure section 1060 to obtain a declaration that the business is exempt from the initiative's warning requirement. Because an actual controversy existed between Baxter and OEHHA about the carcinogenic effects of a chemical in Baxter's products, Baxter was faced with a Hobson's choice. Even though Baxter could demonstrate that its products do not pose a significant risk of causing cancer in humans, it had to provide a stigmatizing warning to the contrary -- which could dissuade the public from using its products -- or risk having to defend itself against being slapped

with an injunction and costly civil penalties. To extract itself from this no-win situation, it was necessary and appropriate for Baxter to obtain a declaration of its rights and obligations under Proposition 65. In order to obtain relief, Baxter had the burden of proving by a preponderance of the evidence that the chemical in its products poses no significant risk of causing cancer in humans. Substantial evidence supports the superior court's finding that Baxter carried its burden by proving that the biological mechanism via which the chemical causes liver cancer in rats and mice does not exist in humans and, thus, the International Agency for Research on Cancer has reclassified the chemical from "'possibly carcinogenic to humans'" to "'not classifiable as to its carcinogenicity to humans.'" Since Baxter established that the chemical poses no significant risk of causing cancer in humans, it was entitled to a judgment declaring that it was exempt from the Proposition 65 warning requirement.

#### STATUTORY BACKGROUND

In 1986, California's voters passed Proposition 65, the "Safe Drinking Water and Toxic Enforcement Act of 1986" (the Act), which is codified in sections 25249.5 through 25249.13. The Act is designed to protect Californians from carcinogens and reproductive toxins. (*AFL-CIO v. Deukmejian* (1989) 212 Cal.App.3d 425, 430-431.) It does so by requiring businesses to give clear and reasonable warnings before exposing the public to a chemical that is on a comprehensive list of chemicals "known to the state to cause cancer or reproductive toxicity," unless a specified

statutory exemption applies. (§ 25249.6.)<sup>1</sup> A business violating or threatening to violate the warning requirement may be enjoined in any court of competent jurisdiction and shall be liable for civil penalties. (§ 25249.7, subds. (a), (b).)

The identification and listing of chemicals known to the state to cause cancer or reproductive toxicity is "pivotal to the entire statutory scheme." (*AFL-CIO v. Deukmejian, supra*, 212 Cal.App.3d at p. 431.) At a minimum, the list, which is published by the Governor on an annual basis, must include substances identified in Labor Code section 6382. (§ 25249.8, subd. (a).) In addition, a chemical must be listed if (1) the state's qualified experts are of the opinion that scientifically valid testing has clearly shown that the chemical causes cancer or reproductive toxicity; (2) a body considered to be authoritative by such experts has formally identified the chemical as causing cancer or reproductive toxicity; or (3) a state or federal government agency has formally required that the chemical be labeled or identified as causing cancer or reproductive toxicity. (§ 25249.8, subds. (a), (b).)

The list must include not only those chemicals that are known to cause cancer in humans, but also those that are known to cause cancer in experimental animals. (*AFL-CIO v. Deukmejian, supra*, 212 Cal.App.3d at pp. 436, 438, fn. 7.) There is a "broad scientific

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<sup>1</sup> Section 25249.6 states: "No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual, except as provided in Section 25249.10."

acceptance of the inference that carcinogenicity in other animals means carcinogenicity in humans.” (*Western Crop Protection Assn. v. Davis* (2000) 80 Cal.App.4th 741, 749; see also *AFL-CIO v. Deukmejian, supra*, 212 Cal.App.3d at p. 438, fn. 7.) And data confirming human carcinogenicity (from epidemiological studies, case reports, and studies on isolated human cells or human tissue) may not exist and may be difficult or impossible to obtain given that it is unethical to test humans. (*AFL-CIO v. Deukmejian, supra*, 212 Cal.App.3d at p. 438, fn. 7.) “[B]ecause of the 20- to 30-year latency period of many human cancers, epidemiological studies do not adequately warn humans and protect them from the risk of exposure to new carcinogens. [Citation.]” (*Ibid.*) Therefore, it is prudent to control exposure to chemicals known to cause cancer in animals as if they had demonstrated effects in humans. (*Ibid.*)

The Governor has designated OEHHA as the lead agency charged with implementing Proposition 65. In this role, OEHHA has the authority to adopt or modify regulations and standards necessary to carry out the Act.<sup>2</sup> (§ 25249.12; *People ex rel. Lungren v. Superior Court* (1996) 14 Cal.4th 294, 310, fn. 6; Cal. Code Regs., tit. 22, § 12102, subd. (o); future references to “Regs.” are to title 22 of the California Code of Regulations.)

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<sup>2</sup> Prior to 1991, the lead agency was the Health and Welfare Agency. (*People ex rel. Lungren v. Superior Court, supra*, 14 Cal.4th at pp. 309-310, fn. 6.) For consistency and ease of reference, actions taken by the Health and Welfare Agency while acting as the lead agency for Proposition 65 shall be referred to as actions taken by OEHHA.

Within OEHHA, there are two committees of the Science Advisory Board--the Carcinogen Identification Committee and the Developmental and Reproductive Toxicant (DART) Identification Committee--which are the "State's qualified experts" who advise and assist the Governor and the director of OEHHA in the implementation of section 25249.8 by rendering opinions regarding whether a chemical has been clearly shown to cause cancer or reproductive toxicity. (Regs., §§ 12102, subds. (c), (t), 12302, subd. (a), 12305, subds. (a), (b).)

Although OEHHA is responsible for implementing the Act, actions to enforce it are brought by California's Attorney General, any district attorney, certain city attorneys, or a city prosecutor with the consent of the district attorney. (§ 25249.7, subd. (c).) If the aforementioned officials fail to take any action despite notice of an alleged violation, any person may bring an enforcement action in the public interest. (§ 25249.7, subd. (d).)

Under certain circumstances, exposures to listed chemicals are exempt from the warning requirement of section 25249.6. As relevant to the present case, section 25249.10 states that "[s]ection 25249.6 shall not apply to any of the following: [¶] . . . [¶] (c) An exposure for which the person responsible can show that the exposure poses no significant risk assuming lifetime exposure at the level in question for substances known to the state to cause cancer . . . based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of such chemical pursuant to subdivision (a) of Section 25249.8. In any action brought to

enforce Section 25249.6, the burden of showing that an exposure meets the criteria of this subdivision shall be on the defendant.”

OEHHA has adopted regulations establishing exposure levels at which specific listed chemicals are deemed to pose no significant risk for purposes of section 25249.10, subdivision (c). (Regs., §§ 12701, subd. (d), 12705.) An exposure level representing “no significant risk” is “one which is calculated to result in one excess case of cancer in an exposed population of 100,000, assuming lifetime exposure at the level in question . . . .” (Regs., § 12703, subd. (b).) A no significant risk level generally is determined via a quantitative risk assessment “based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for listing the chemical as known to the state to cause cancer.” (Regs., §§ 12703, subd. (a), 12705, subd. (b).) But another regulation promulgated by OEHHA states: “Nothing in this article shall preclude a person from using evidence, standards, risk assessment methodologies, principles, assumptions or levels not described in this article to establish that a level of exposure to a listed chemical poses no significant risk.” (Regs., § 12701, subd. (a).)

Any interested person may ask OEHHA to issue an interpretive guideline concerning any subject related to the Act, which may be treated by the agency as a request for a safe use determination. (Regs., § 12203, subs. (a), (c).) As part of its responsibility to provide such guidance, OEHHA will consider the applicability of the Act, or the exemptions specified therein, to business activities or prospective business activities. (Regs., § 12204,

subd. (a).) "A safe use determination issued by [OEHHA] represents the state's best judgment concerning the application of the Act to the particular facts presented in the request." (Regs., §§ 12204, subd. (a), 12102, subd. (s).) However, a safe use determination is advisory only; therefore, it does not affect the authority of those authorized by section 25249.7 to prosecute violations of the Act, "nor does it affect the responsibility of courts to interpret the Act and apply the provisions of the Act to particular facts." (Regs., § 12204, subd. (a).)

#### FACTUAL AND PROCEDURAL BACKGROUND

Baxter manufactures prescription medical devices, such as intravenous bags and tubing, which contain a chemical plasticizer, di(2-ethylhexyl)phthalate (DEHP). Because the medical devices come in contact with the human body, Baxter exposes patients to DEHP within the meaning of the Act. (Regs., § 12102, subd. (i).)<sup>3</sup>

It is undisputed that DEHP causes liver cancer in rats and mice, and that DEHP is on Proposition 65's list of chemicals known to the state to cause cancer or reproductive toxicity. (Regs., § 12000, subd. (b).) In 1987, the Scientific Advisory Panel (the predecessor to OEHHA's Science Advisory Board) added DEHP to the list solely on the basis of animal studies, despite public comments indicating that DEHP should not be listed because it causes cancer only in mice and rats and it is unlikely to be a

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<sup>3</sup> California Code of Regulations, title 22, section 12102, subdivision (i), states in part: "'Expose' means to cause to ingest, inhale, contact via body surfaces or otherwise come into contact with a listed chemical."

human carcinogen. OEHHA established a "no significant risk" level for DEHP of 80 micrograms a day (later raised to 310 micrograms a day).

In January 1999, Baxter submitted an administrative petition asking OEHHA to (1) promulgate a regulation finding there is insufficient evidence that exposure to DEHP poses a significant risk of cancer in humans and, thus, subdivision (c) of section 25249.10 exempts DEHP from the warning requirement; (2) promulgate an exemption from the warning requirement for DEHP prescription medical devices where human exposure is non-oral; (3) make a determination that DEHP presents no significant risk of cancer by non-oral routes of exposures; and (4) revise Proposition 65's listing of DEHP to reflect "DEHP by oral route of exposure."

Baxter claimed that the animal data which is the basis for listing DEHP as known to cause cancer are irrelevant to predicting human risk because the biological mechanism by which DEHP causes liver cancer in rats and mice does not operate in humans; hence, there is no significant risk that exposure to DEHP causes cancer in humans.

In March 1999, OEHHA denied the petition, finding that Baxter's evidence did not "point[] toward a determination that human exposure to any level of DEHP is without carcinogenic risk. Rather, the literature presents data that leave open the possibility of human sensitivity to DEHP's carcinogenic effects. . . . Thus, based on the available scientific evidence, OEHHA is not willing to take the requested regulatory action."

OEHHA also found that it lacked the authority to take some of the actions requested by Baxter. In OEHHA's view, despite its status as the lead agency, it did not have the authority to modify listings or remove chemicals from the Act's list of its own volition. Rather, Baxter needed to seek such relief from the Carcinogen Identification Committee of the Scientific Advisory Board via a published mechanism for reconsideration of agents on the Proposition 65 list.

In May 1999, Baxter filed a petition for writ of mandate, challenging OEHHA's denial of Baxter's administrative petition and seeking to compel OEHHA to promulgate a regulation declaring that prescription medical devices containing DEHP pose no significant risk of cancer in humans and, therefore, a Proposition 65 warning is not required for such devices. Baxter also filed a complaint for declaratory relief, requesting a declaration by the superior court that (1) "the warning requirements of Proposition 65 applied in the context of prescription medical devices alter and diminish [both] the legal obligations established by the law of informed consent" and "the legal obligations of prescription medical device manufacturers," and (2) Proposition 65 warnings are not required for prescription medical devices.

Thereafter, the parties stipulated that "the issues presented to the Court for determination in this phase of the proceedings were limited to Baxter's request that [OEHHA] make a determination or promulgate a regulation declaring that prescription medical devices containing DEHP pose no significant risk of cancer to humans and that there accordingly is no required cancer warning for

such products . . . ." (Fn. omitted.) The remaining issues would be addressed in further proceedings.

In April 2000, the superior court denied the petition for writ of mandate. The court noted that Baxter had made a detailed and compelling scientific presentation in support of its position that DEHP cannot cause cancer in humans, and that OEHHA's response to this issue was unconvincing. Nevertheless, the court ruled, among other things, that nothing in Proposition 65 or its implementing regulations required OEHHA to make the findings or promulgate the regulation requested by Baxter, including the request that OEHHA change DEHP's listing to reflect it causes cancer only by oral route of exposure, and that OEHHA did not abuse its discretion in denying Baxter's administrative petition.

Baxter then sought leave of court to amend its complaint for declaratory relief to add a cause of action seeking a declaration that exposure to DEHP from prescription medical devices poses no significant risk of cancer to humans and, thus, Proposition 65 warning requirements do not apply to such exposures pursuant to section 25249.10. Baxter pointed out that the International Agency for Research on Cancer, which is recognized by pertinent regulations as an authoritative body on the identification of chemicals causing cancer (Regs., § 12306, subd. (m)), had recently determined that the biological mechanism by which DEHP increases the incidence of liver tumors in rats and mice is not relevant to, and does not operate in, humans.

Baxter argued a justiciable controversy existed and that Baxter was not simply seeking an advisory opinion, given that it

had already been the target of Proposition 65 enforcement actions by private party enforcers and the State of California. Baxter asserted that it should not have to wait to be sued again and then raise the no significant risk of cancer exemption in section 25249.10 as a defense.

The superior court granted Baxter leave to file an amended complaint.

In its amended complaint, Baxter alleged, among other things, that scientific evidence of comparable validity to the evidence forming the basis for listing DEHP demonstrated that exposure to DEHP from prescription medical devices poses no significant risk of cancer to humans. Accordingly, Baxter asked the superior court to declare that no significant risk of cancer existed and that Baxter did not have to comply with the warning requirements of Proposition 65.

At trial, Baxter presented evidence supporting the following theory: DEHP induces cancer in rats and mice through a combination of increased cell proliferation and suppression of apoptosis (i.e., programmed cell death), and possibly oxidative stress. DEHP induces these three effects through activation of the receptor known as the peroxisome proliferator activated receptor-alpha (PPAR $\alpha$ ). In rats and mice, the metabolites of DEHP enter the liver cells and bind to and activate PPAR $\alpha$  receptors. Activation of PPAR $\alpha$  causes the receptor complex to enter the nucleus and bind to peroxisome proliferator response elements (PPRE), thereby initiating gene transcription. It is the activation of PPAR $\alpha$  that causes alteration of gene expression, which leads to increased cell

proliferation, suppression of apoptosis, oxidative stress, and ultimately the development of cancer. However, this process does not operate in humans exposed to DEHP. In fact, multiple studies have disclosed that DEHP does not increase cell proliferation, suppress apoptosis, or increase oxidative stress in humans exposed to DEHP. This is so because humans have insufficient levels of PPAR $\alpha$  to induce the full battery of genes necessary for the induction of cancer. In addition, human PPREs do not function in the same manner as those of rodents when exposed to DEHP. As a consequence, the altered gene expression, which occurs in rats and mice exposed to DEHP, does not occur in humans.

OEHHA did not attempt to demonstrate that exposure to DEHP actually causes cancer in humans. Instead, it submitted evidence attempting to cast doubt on Baxter's theory of rodent carcinogenesis by pointing out uncertainties or gaps in the data. It also demonstrated that the understanding of rodent carcinogenesis and the differences between rodent and human biology is not complete yet, and that humans appear to be responsive to some peroxisome proliferators.

In October 2002, the superior court granted the request for declaratory relief that Baxter sought in its amended complaint.

The court noted that Baxter had mounted a three-prong basis for declaratory relief, by alleging its evidence demonstrated that DEHP does not pose a significant risk of cancer in humans because (1) the biological mechanism by which DEHP causes liver cancer in laboratory animals does not function in humans; (2) even if the mechanism of carcinogenesis operates in humans, persons exposed

to DEHP under all conceivable conditions receive a dose that is insufficient to cause cancer; and (3) humans have been exposed to DEHP for many years, sometimes at relatively large doses, and have not developed cancer as a result. The court ruled that Baxter had carried its burden of proof as to its first contention, but not as to its second and third contentions.

The court found that the preponderance of the evidence demonstrated how exposure to DEHP causes liver cancer in rats and mice; the evidence showed that the biological mechanism by which this occurs does not occur in humans; and, therefore, it is more probable than not that exposure to DEHP does not pose a significant risk of cancer to humans. The court also noted that the International Agency for Research on Cancer (IARC) has concluded that the mechanism of carcinogenesis operating in rats and mice does not operate in humans and, on this basis, IARC has reclassified DEHP from "'possibly carcinogenic to humans'" to "'not classifiable as to its carcinogenicity to humans.'"

The court was not persuaded by OEHHA's opposing evidence, finding that it was insufficient to overcome Baxter's evidence and that "[n]o alternative mechanism by which [DEHP could cause cancer] has been sufficiently delineated or investigated so as to be anything other than speculation or unconfirmed hypothesis at this time." OEHHA simply had demonstrated there is some degree of contradictory evidence, there is a degree of reasonable doubt regarding Baxter's proposed model of carcinogenesis, and that much is still unknown.

Accordingly, the court entered judgment declaring that DEHP poses no significant risk of cancer to humans and, thus, no warning of carcinogenicity was required to be given to persons exposed to this chemical. The court also entered judgment on its previous ruling denying Baxter's petition for writ of mandate.

#### DISCUSSION

OEHHA raises a multitude of arguments to support its claim that the superior court erred in issuing a declaratory relief judgment declaring "[DEHP] poses no significant risk of cancer to humans, so that, pursuant to [Proposition 65] no warning of carcinogenicity is required to be given to persons exposed to this chemical." In OEHHA's view, declaratory relief was not appropriate for a variety of reasons.

#### I

OEHHA asserts that by releasing Baxter from "its warning obligations" and by "arguably" releasing "all other companies from all other obligations that spring from DEHP's listing as a carcinogen," the superior court's declaration "amounts to a de facto de-listing of DEHP as known to the state to cause cancer."

Having so characterized the judgment, OEHHA argues that the declaration impermissibly "circumvent[ed] the constitutional and policy considerations that underlie deference to agency decision making." OEHHA explains: "[I]t is the task of the scientists and physicians comprising the State's Qualified Experts and those on OEHHA's staff" to determine whether a chemical is included on the Proposition 65 warning list. "Allowing a trial court to make the categorical determination of human carcinogenicity *de novo* removes

fundamental regulatory and administrative functions from the State's Qualified Experts and OEHHA and places them in the judiciary. By engaging in this kind of decision making, a court usurps functions delegated to administrative bodies in violation of the principle of separation of powers and fails to recognize OEHHA's substantial scientific and technical expertise. Such judicial decision making also undermines the principle of precaution embodied in Proposition 65, and, in effect, mandates the way in which the State's Qualified Experts and OEHHA must make decisions in the future, if they desire their decisions to withstand judicial review through declaratory relief. 'Such a judgment ruptures the parameters of declaratory relief; it represents an abuse of judicial discretion.' (See *California Optometric Association [v. Lackner* (1976)] 60 Cal.App.3d [500,] 509.)"

The problem with this contention is its faulty premise that the superior court's declaration "amounts to a de facto de-listing of DEHP as known to the state to cause cancer."

As we have noted, the Proposition 65 list includes chemicals that are known to cause cancer in animals, even though it has not been definitively established that the chemicals will cause cancer in humans. This is so because it is unethical to test humans and, given the long latency periods of many human cancers, it would pose an undue risk to the public to require definitive proof that a chemical causes cancer in humans. (See *AFL-CIO v. Deukmejian*, *supra*, 212 Cal.App.3d at pp. 436, 438, fn. 7.) Since there is a "broad scientific acceptance of the inference that carcinogenicity in other animals means carcinogenicity in humans" (*Western Crop*

*Protection Assn. v. Davis, supra*, 80 Cal.App.4th at p. 749), it is prudent to control exposure to chemicals known to cause cancer in animals as if they had demonstrated effects in humans. (*AFL-CIO v. Deukmejian, supra*, 212 Cal.App.3d at pp. 438-439, fn. 7.)

It is uncontested that DEHP causes liver cancer in rats and mice. For this reason alone, DEHP was placed on the Proposition 65 list, despite public comments that it causes cancer only in animals and is unlikely to cause cancer in humans.

Baxter did not seek a declaration that DEHP must be removed from the Proposition 65 warning list on the ground that it has not been shown to cause cancer at all. Rather, Baxter's request for declaratory relief cited section 25249.10, subdivision (c), which states that Proposition 65 warnings "shall not apply" when, "based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of such chemical," the person responsible for the exposure shows that it "poses no significant risk assuming lifetime exposure at the level in question for substances known to the state to cause cancer . . . ."

Based upon evidence that humans do not have the biological mechanism which causes rats and mice to contract liver cancer, Baxter obtained a declaration that (1) exposure to DEHP from prescription medical devices poses no significant risk of cancer in humans, (2) therefore, Proposition 65 warning requirements do not apply to such exposures.

Contrary to OEHHA's claim, the superior court's judgment does not "'second-guess'" the administrative decision to include DEHP

on the Proposition 65 list. And nothing in the judgment requires OEHHA to remove DEHP from the list of chemicals known to the state to cause cancer.

Although OEHHA asserts that the superior court's declaration "arguably" releases "all other companies from all other obligations that spring from DEHP's listing as a carcinogen," OEHHA then intimates that the declaration has no collateral estoppel effect with respect to the Attorney General in an enforcement action against other businesses using DEHP in their products. Indeed, OEHHA provides no analysis and authority showing that anyone bringing an enforcement action against someone other than Baxter will be collaterally estopped from refuting a defensive claim that exposure to DEHP does not create a significant risk of cancer in humans. OEHHA does not even discuss any of the elements of collateral estoppel or res judicata, or make any showing that those elements establish that the superior court's decision is binding with respect to other companies or persons. Hence, the issue is waived. (*In re Marriage of Nichols* (1994) 27 Cal.App.4th 661, 672-673, fn. 3; *Atchley v. City of Fresno* (1984) 151 Cal.App.3d 635, 647 ["Where a point is merely asserted by appellant's counsel without any argument of or authority for the proposition, it is deemed to be without foundation and requires no discussion by the reviewing court"].)

In sum, OEHHA has failed to establish that the judgment results in a "de facto de-listing" of DEHP, as opposed to simply a determination that the exemption from the Proposition 65 warning requirements set forth in section 25249.10, subdivision (c), applies

to prescription medical devices containing DEHP that are made by one company, Baxter, because Baxter presented persuasive evidence that exposure to DEHP in its products poses no significant risk of developing cancer in humans. In making this determination, the court did not perform an agency function because OEHHA concedes it is not charged with determining, in the first instance, whether the statutory exemption applies to a particular product; in OEHHA's words, "this determination is for the court . . . ."

Having failed to establish the premise of its argument, OEHHA has failed to demonstrate that the judgment improperly infringed on the administrative decision to place DEHP on the Proposition 65 list.

## II

OEHHA points out that the superior court rejected Baxter's mandamus action which challenged OEHHA's denial of Baxter's administrative petition asking OEHHA to promulgate a regulation finding there is insufficient evidence that exposure to DEHP poses a significant risk of cancer in humans. OEHHA then complains that Baxter simply changed the name of its petition for writ of mandamus to a claim for declaratory relief, thus "obtain[ing] from the trial court a *de novo* hearing on its argument that DEHP does not cause cancer in humans, a non-deferential standard of review, and a more favorable result." According to OEHHA, Baxter in effect did an end run around the superior court's denial of Baxter's petition for writ of administrative mandamus and that in granting declaratory relief, the court entered an inconsistent order which "fail[ed] to defer

to OEHHA's [administrative] decision that the current data are insufficient to conclude that DEHP cannot cause cancer in humans."

Contrary to the picture painted by OEHHA, in denying Baxter's petition for writ of mandamus, the superior court did *not* rule that OEHHA correctly found the evidence presented to it in the administrative action was insufficient to conclude that DEHP cannot cause cancer in humans. Rather, the court ruled that the pertinent statutes and regulations did not impose a mandatory duty on OEHHA to promulgate the regulation sought by Baxter, even if Baxter presented compelling proof that DEHP does not cause cancer in humans. Indeed, the court found that if the applicable statutes and regulations had required OEHHA to promulgate such a regulation upon adequate proof, OEHHA's response to Baxter's evidence "would not have passed muster." Hence, the court's ruling on Baxter's complaint for declaratory relief was not inconsistent with the court's denial of Baxter's petition for writ of mandamus.

And, contrary to OEHHA's suggestion, the superior court did *not* engage in a *de novo* review of OEHHA's administrative decision. It simply determined that, because Baxter presented persuasive evidence that exposure to DEHP in its products poses no significant risk of causing cancer in humans, the warning requirement exemption of section 25249.10, subdivision (c), applies to the prescription medical devices containing DEHP that are manufactured by Baxter. In making this determination, the court did not fail to defer to OEHHA's administrative decision because, as we noted earlier, OEHHA concedes it is not charged with determining, in the first instance,

whether the statutory exemption applies to a particular product; in OEHHA's words, "this determination is for the court . . . ."

### III

Although OEHHA concedes that it is for a court to determine whether the Proposition 65 warning exemption set forth in section 25249.10, subdivision (c), applies to a particular product, OEHHA argues the superior court should not have made that determination in this action. This is so, OEHHA argues, because, in its view, the exposure exemption can be raised only defensively in an enforcement action under section 25249.7; it cannot be raised preemptively in a declaratory relief action under Code of Civil Procedure section 1060.

To put the contention in context, we reiterate pertinent parts of Proposition 65's statutory scheme. Section 25249.6 prohibits a business from knowingly and intentionally exposing any individual to a chemical known to the state to cause cancer "without first giving clear and reasonable warning to such individual, except as provided in Section 25249.10." Section 25249.7 states that any business violating or threatening to violate section 25249.6 may be enjoined by a court, and found liable for a civil penalty, in what is known as an enforcement action brought by the Attorney General of California, local prosecutors, or any person in the public interest if the Attorney General or local officials decline to prosecute. Section 25249.10, subdivision (c), states that the warning requirement of section 25249.6 does not apply to an exposure for which the business responsible can show that the exposure poses no significant risk assuming certain conditions specified in the

statute, and that "[i]n any action brought to enforce Section 25249.6, the burden of showing that an exposure meets the criteria of this subdivision shall be on the defendant."

OEHHA relies primarily on *Filarsky v. Superior Court* (2002) 28 Cal.4th 419 (hereafter *Filarsky*) to support its contention that raising the section 25249.10, subdivision (c), exposure exemption as a defense to an enforcement action is the exclusive means to litigate whether the exposure poses no significant risk.

In *Filarsky*, a person asked a city to disclose documents pursuant to the California Public Records Act (the CPRA) (Gov. Code, § 6250 et seq.). When the city refused, the person indicated that he intended to file a judicial proceeding under the CPRA to compel disclosure. But, before he did so, the city filed a declaratory relief action under Code of Civil Procedure section 1060, seeking a declaration that the city was not required to disclose the documents. (*Filarsky, supra*, 28 Cal.4th at p. 423.)

*Filarsky* held that the superior court abused its discretion in granting the city declaratory relief pursuant to Government Code section 1060. The court explained: The CPRA contained specific procedures for seeking a judicial determination of the obligation to disclose records. (Gov. Code, §§ 6258, 6259.) Those procedures differed from ordinary declaratory relief actions in at least four ways. The CPRA authorized only citizens, not public agencies, to seek declaratory relief regarding the public agency's duty of disclosure; it included a type of fast track procedure; a prevailing citizen could be awarded attorney fees but would not have to pay fees and costs to a prevailing public defendant unless the action

was frivolous; and appellate review of the superior court's decision was expedited. (*Filarsky, supra*, 28 Cal.4th at pp. 428-429.) Permitting the city to file a declaratory relief action under Code of Civil Procedure section 1060 would circumvent the CPRA's specific statutory protections and incentives for individuals seeking disclosure of public records. (*Id.* at pp. 429-433.) It also would require individuals to defend civil actions that they otherwise might not have commenced and discourage them from seeking records pursuant to the CPRA. (*Ibid.*) For these reasons, it is apparent that the Legislature intended the provisions of the CPRA to be the exclusive means to obtain a judicial determination of the obligations imposed by the CPRA. (*Id.* at pp. 423, 433.) Accordingly, the superior court abused its discretion by granting declaratory relief pursuant to Code of Civil Procedure section 1060. (*Ibid.*)

OEHHA claims the same result should apply with respect to Proposition 65. OEHHA raises various arguments in support of this contention: (1) "there is no provision in Proposition 65 expressly authorizing declaratory relief of any kind. The only section allowing for court action is section 25249.7, a detailed provision that authorizes only actions to enforce, not avoid, the requirements of Proposition 65"; (2) "allowing preemptive declaratory relief claims to establish the exposure exemption would eliminate many of the incentives and protections in Proposition 65's enforcement provision and would thwart its purposes. For example, the enforcement provision gives the Attorney General in his independent capacity an important role

in controlling and overseeing the enforcement of Proposition 65. . . . If any person can bring a preemptive declaratory relief claim, . . . the Attorney General's enforcement prerogative will be impaired by interfering with his discretionary power to choose whether to become involved in Proposition 65 enforcement actions"; (3) "Proposition 65 and its regulations reflect the voters' intent that application of the exposure exemption be determined in the context of an enforcement action, in response to a specific allegation of violation of the Act, and not in a preemptive action seeking broad declaratory relief"; (4) "reading the Act to permit preemptive declaratory relief would render many of the Act's supporting regulations superfluous"; and (5) "given the hundreds of listed chemicals and the millions of products that may cause exposures to these chemicals, an interpretation of the exposure exemption to allow for preemptive declaratory relief claims would substantially interfere with administrative functions. OEHHA would be called away from its regulatory duties . . . to defend actions filed at the pleasure of those seeking unregulated exposures. Such an interpretation would, in addition, convert the court system into a Proposition 65 exposure permitting center."

Despite a bit of hyperbole, these arguments are superficially appealing. However, as we will explain, they do not survive close scrutiny.

The pertinent provisions of Proposition 65 do not share the characteristics of the CPRA that *Filarsky* found to be persuasive indicators of a legislative intent to exclude declaratory relief actions under Code of Civil Procedure section 1060. In particular,

Proposition 65 does not contain specific statutory mechanisms for seeking declaratory relief. Nor does Proposition 65 have any procedural protections for the public, comparable to those in the CPRA, that would be circumvented if persons using listed chemicals in their products were permitted to seek preemptive declaratory relief under Code of Civil Procedure section 1060, rather than raise the exemption as a defense in an enforcement action.

The fact there is no provision in Proposition 65 expressly authorizing declaratory relief does not, as OEHHA argues, suggest the Legislature intended to preclude declaratory relief. Rather, it was the *existence* of such language in the CPRA which led our Supreme Court to conclude that CPRA's provisions were intended to be the exclusive means to obtain a judicial determination regarding the obligations imposed by the CPRA. It follows that the absence of such language in Proposition 65 indicates that the Legislature did not intend the Act's provisions to be the exclusive means to obtain a judicial determination of a business's responsibilities under Proposition 65.

Although OEHHA claims that allowing preemptive declaratory relief to establish the exposure exemption would "eliminate many of the incentives and protections in Proposition 65's enforcement provision and would thwart its purposes," OEHHA presents just one example to support its claim. According to OEHHA, permitting such a declaratory relief action would interfere with the Attorney General's discretionary role in controlling and overseeing the enforcement of Proposition 65.

This contention is not persuasive given that this is not an enforcement proceeding and the Attorney General is representing OEHHA in this declaratory relief action. OEHHA has failed to show why the Attorney General's involvement in this litigation is not sufficient to fulfill his role in ensuring compliance with the warning requirement of Proposition 65.

OEHHA asserts that regulations implementing Proposition 65 provide several options by which a person or business can obtain pre-enforcement guidance from the agency about whether the party's actions subject it to liability under the Act. Specifically, OEHHA points to regulations concerning the calculation of "no significant risk levels" (NSRLs), including OEHHA's determination that exposure to 310 micrograms per day of DEHP poses no significant risk of cancer for purposes of section 25249.10, subdivision (c). (Regs., §§ 12701, subs. (a), (d), 12703, 12705, subs. (a), (b)(1).) OEHHA argues that Proposition 65 should not be interpreted to permit a declaratory relief action because this would render these supporting regulations superfluous.

However, OEHHA points to nothing in the regulations which compels the conclusion that permitting a declaratory relief action concerning whether a particular chemical poses a significant risk of cancer in humans either conflicts with the statutory scheme or renders superfluous the implementing regulations. Although the regulations cited by OEHHA purport to set forth NSRLs for specific chemicals and explain the method for establishing NSRLs for the purposes of section 25249.10, subdivision (c), the regulations state: "Nothing in this article shall preclude a person from using

evidence, standards, risk assessment methodologies, principles, assumptions or levels not described in this article to establish that a level of exposure to a listed chemical poses no significant risk." (Regs., § 12701, subd. (a).) This indicates that a business is not bound by OEHHA's determination of a specific chemical's NSRL, and that the business may show the chemicals in its products do not pose a significant risk of cancer. In fact, OEHHA concedes that its regulatory establishment of a NSRL is only a determination that an exposure below the level is not a significant risk. In OEHHA's words, its establishment of a NSRL "expressly is not a determination that any level above the NSRL poses a significant risk."

Moreover, seeking pre-enforcement guidance from OEHHA concerning the safe use of a chemical and the application of the NSRL exemption in the Act does not ensure that an enforcement action will not be brought against the person seeking guidance. As OEHHA concedes, its safe use determination is "advisory only" and is not binding in an enforcement action. (Regs., § 12204, subd. (a).) Thus, the only way for a business to obtain a binding pre-enforcement determination that a Proposition 65 warning is not required with respect to exposing the public to certain chemicals is via a declaratory relief judgment from the superior court.

In sum, OEHHA has failed to demonstrate that a declaratory relief action renders superfluous the implementing regulations upon which OEHHA relies.

OEHHA also argues that allowing preemptive declaratory relief actions would result in a multitude of lawsuits from businesses regarding listed chemicals, which would be unduly time-consuming

for OEHHA and interfere with its regulatory duties. But OEHHA points to no evidence of the number of persons or businesses who typically are subjected to enforcement actions or who seek interpretive guidance concerning specific chemicals. Hence, its claim that permitting preemptive declaratory relief actions would result in an avalanche of such actions is entirely speculative. Moreover, OEHHA has not presented any argument or legal analysis demonstrating that the burden of addressing whether exposure to a chemical presents a significant risk of cancer is significantly increased if OEHHA has to address this issue in a declaratory relief action rather than in response to an interpretive guideline request. (Regs., § 12203.)

For all the reasons stated above, OEHHA has failed to establish that Proposition 65 does not allow a business to bring a declaratory relief action under Code of Civil Procedure section 1060 for the purpose of determining whether the business is exempted from the warning requirement of Proposition 65.

#### IV

Next, OEHHA claims there was no actual controversy between OEHHA and Baxter and, therefore, the superior court abused its discretion in granting declaratory relief. We disagree.

Code of Civil Procedure section 1060 provides in pertinent part: "Any person . . . who desires a declaration of his or her rights or duties with respect to another . . . may, in cases of actual controversy relating to the legal rights and duties of the respective parties, bring an original action . . . in the superior court for a declaration of his or her rights and duties . . . ."

He or she may ask for a declaration of rights or duties, either alone or with other relief; and the court may make a binding declaration of these rights or duties, whether or not further relief is or could be claimed at the time. The declaration may be either affirmative or negative in form and effect, and the declaration shall have the force of a final judgment. The declaration may be had before there has been any breach of the obligation in respect to which said declaration is sought."

"The 'actual controversy' referred to in this statute is one which admits of definitive and conclusive relief by judgment within the field of judicial administration, as distinguished from an advisory opinion upon a particular or hypothetical state of facts. The judgment must decree, not suggest, what the parties may or may not do. [Citations.]" (*Selby Realty Co. v. City of San Buenaventura* (1973) 10 Cal.3d 110, 117.) Moreover, declaratory relief "'operates prospectively, and not merely for the redress of past wrongs. It serves to set controversies at rest before they lead to repudiation of obligations, invasion of rights or commission of wrongs; in short, the remedy is to be used in the interests of preventive justice, to declare rights rather than execute them.'" [Citations.]" (*Babb v. Superior Court* (1971) 3 Cal.3d 841, 848.)

Accordingly, "'[t]he purpose of a declaratory judgment is 'to serve some practical end in quieting or stabilizing an uncertain or disputed jural relation' [citations].' Another purpose is to liquidate doubts with respect to uncertainties or controversies

which might otherwise result in subsequent litigation [citation].”  
(*Bess v. Park* (1955) 132 Cal.App.2d 49, 52.)

OEHHA argues that because it is not responsible for enforcement actions against businesses which violate the warning requirement of Proposition 65 (see § 25249.7), the fact Baxter may be subjected to an enforcement action does not create a controversy between Baxter and OEHHA. Relying on *BKHN, Inc. v. Department of Health Services* (1992) 3 Cal.App.4th 301 (hereafter *BKHN*), OEHHA also claims that it has no actual controversy with Baxter because OEHHA is not responsible for determining whether a defendant in an enforcement action has a viable defense under the exemption set forth in section 25249.10, subdivision (c).

In *BKHN, supra*, 3 Cal.App.4th 301, the Department of Health Services (DHS) submitted an invoice to a corporation and the county to recover the costs of cleaning up a park contaminated with mercury. DHS asserted that under federal law, responsible parties could be held jointly and severally liable for site cleanup costs. The corporation filed a complaint seeking a declaration that the costs were to be apportioned equally under the Hazardous Substances Account Act (the HSAA). (§§ 25300-25395.) DHS demurred to the complaint on the grounds there was no actual controversy between the parties, the matter was not yet ripe for adjudication, and there was no immediate threat of harm because DHS had waived the right to offset the amounts it demanded from any tax refund due. (*BKHN, supra*, 3 Cal.App.4th at pp. 305-307.) The trial court sustained the demurrer, concluding a declaration was not necessary or proper at the time under the circumstances. (*Id.* at p. 307.)

*BKHN* affirmed, holding the matter was not ripe for resolution because no “‘definitive and conclusive relief’” could be granted. A declaration that liability under the HSAA was several only would not affect the corporation’s ultimate obligations because DHS could elect to proceed under a federal statute which permitted joint and several liability. (*BKHN, supra*, 3 Cal.App.4th at pp. 305, 310.) *BKHN* also held there was no actual controversy capable of final, meaningful resolution because DHS had no authority to finally determine whether the corporation would indeed be liable for cleanup costs, and DHS’s interpretation of the HSAA would not govern the extent of the corporation’s liability. Therefore, a decree stating DHS could seek from the corporation only that portion of the costs attributable to contamination caused by the corporation “would be premature and meaningless if it were made before the extent of liability was determined.” (*Id.* at p. 311.) Moreover, even if the trial court declared that the HSAA prohibits a finding of joint and several liability, this would not provide the corporation with any certainty regarding its ultimate liability or what portion of the cleanup costs that it would have to bear. (*Id.* at p. 312.) In sum, *BKHN* determined it was inappropriate to speculate concerning the HSAA’s application to hypothetical situations. (*Ibid.*)

Here, unlike in *BKHN*, the superior court’s judgment provides Baxter with definitive and conclusive relief because the declaration that Baxter is not required to give a Proposition 65 warning protects Baxter from subsequent enforcement actions. Even if OEHHA does not initiate or pursue enforcement actions against Proposition 65

violators, a controversy exists between Baxter and OEHHA because (1) they dispute the appropriate "no significant risk level" for DEHP, and (2) OEHHA set the NSRL at a level that subjects Baxter to an enforcement action if it does not provide a Proposition 65 warning for its products containing DEHP.

OEHHA is wrong in suggesting no "'live controversy'" existed because Baxter could have made an administrative request for OEHHA to reevaluate and raise the NSRL for DEHP (see Regs., § 12705, subd. (c))<sup>4</sup> but did not do so. An aggrieved party is not required to exhaust administrative remedies before bringing a declaratory relief action where the party can positively state what the administrative agency's decision would be. (*Venice Town Council, Inc. v. City of Los Angeles* (1996) 47 Cal.App.4th 1547, 1567.) Baxter demonstrated in two ways that OEHHA would have rejected a request by Baxter to reevaluate the NSRL for DEHP. First,

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<sup>4</sup> Title 22 of California Code of Regulations, subsection (c), provides: "Unless a specific regulatory level for a chemical known to the state to cause cancer has been established in subsection (b) [which includes DEHP], levels of exposure deemed to pose no significant risk may be determined by the lead agency based on state or federal risk assessments. [¶] (1) Any interested party may request the lead agency to reevaluate a level established in this subsection based on scientific considerations that indicate the need for the lead agency to develop its own risk assessment or to conduct a detailed review of the risk assessment used to derive the level in question. Such request shall be made in writing, and shall include a description of the scientific considerations that indicate the need for the lead agency to develop its own risk assessment or to conduct a detailed review of the risk assessment used to derive the level in question. The lead agency may establish a level for the chemical in question in subsection (b) as it deems necessary."

the record shows that the DEHP Healthcare Industry Task Force had recently asked OEHHA to raise the NSRL for DEHP to 140,000 micrograms per day based on a theory that was similar, if not identical, to the one presented by Baxter about the lack of a sufficient PPAR $\alpha$  mechanism in humans. However, OEHHA raised the NSRL to only 310 micrograms per day on the ground that it was inappropriate to conclude yet that humans are unresponsive to peroxisome proliferators and, thus, to conclude that there was no possibility DEHP could not cause cancer in humans. Second, OEHHA rejected Baxter's PPAR $\alpha$  theory when it denied Baxter's administrative petition seeking a regulation expressly stating that DEHP does not pose a significant risk of cancer in humans. Although the superior court found that OEHHA lacked the authority to issue the specific regulation requested by Baxter, OEHHA's rejection of Baxter's theory demonstrates it would not have responded favorably to a request to raise the NSRL to a level that would protect Baxter against enforcement actions concerning its medical products containing DEHP.

Because an irreconcilable controversy existed between OEHHA and Baxter over the NSRL set by OEHHA for DEHP, Baxter was compelled either to provide a stigmatizing warning regarding its products even though it could show DEHP does not cause cancer in humans, or risk being subjected to an enforcement action and costly civil penalty if its PPAR $\alpha$  theory is rejected in an enforcement action.

Declaratory relief was necessary and proper to prevent Baxter from having to make this Hobson's choice (see *Zeitlin v. Arnebergh*

(1963) 59 Cal.2d 901, 906 (hereafter *Zeitlin*) and to enable Baxter to obtain a declaration of its rights and obligations under the Act. (*Californians for Native Salmon etc. Assn. v. Department of Forestry* (1990) 221 Cal.App.3d 1419, 1427 (hereafter *Californians for Native Salmon*) ["[d]eclaratory relief is appropriate to obtain judicial clarification of the parties' rights and obligations under applicable law"].)

For example, in the 1960's Jacob Zeitlin was a bookseller who wanted to sell "Tropic of Cancer" in his store but was prevented from doing so because he feared the city attorney would institute criminal proceedings against him. (*Zeitlin, supra*, 59 Cal.2d at p. 906.) In the words of the California Supreme Court, "[t]o deny Zeitlin, a legitimate businessman, an opportunity for declaratory relief is to force him to choose between undesirable alternatives. If he continues to sell the book he incurs the risk of criminal prosecution and faces the fine, jail sentence, or both, which may be imposed if he is found guilty, or he sustains the accompanying stigma which attaches even though he may ultimately be found innocent. As an alternative he may assume the role of self-appointed censor, prodded by the city attorney, and discontinue the sale of any book which could possibly offend the latter." (*Ibid.*, fns. omitted.) Because these facts demonstrated the existence of an actual controversy, an action for declaratory relief was proper. (*Id.* at pp. 907-908.)<sup>5</sup>

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<sup>5</sup> In a footnote in its reply brief, OEHHA contends that the ruling in *Zeitlin* was based on the bookseller's First Amendment

Since Baxter was presented with a Hobson's choice akin to that faced by Zeitlin, it follows that Baxter was entitled to a declaration of its rights and obligations under Proposition 65. (See also *Chas. L. Harney, Inc. v. Contractors' Bd.* (1952) 39 Cal.2d 561, 564 [plaintiff was not required to violate an administrative regulation and subject itself to possible criminal prosecution or disciplinary action in order to obtain a declaration of its rights and duties]; *Malish v. City of San Diego* (2000) 84 Cal.App.4th 725, 728 [plaintiff adequately pleaded an actual controversy by alleging he was presently and continually subject to revocation of his local permit, to criminal prosecution, and to other enforcement actions based on the City's ordinances which were preempted by state law].)

OEHHA argues Baxter has failed to show that the rationale of *Zeitlin* applies when a civil penalty, as opposed to a criminal

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interests and that "Baxter did not attempt to establish that the warning requirement of Proposition 65 infringes upon its First Amendment or any other constitutional right." Since "speech" includes written expression (*Gerawan Farming, Inc. v. Lyons* (2000) 24 Cal.4th 468, 484), the Proposition 65 requirement that Baxter provide a written warning stating its product includes a substance known to cause cancer implicates Baxter's First Amendment freedom of speech. Baxter's failure to more fully explicate its legal theory, with supporting citations to the United States and California Constitutions, is most likely due to OEHHA's failure to demur to Baxter's complaint on the ground that declaratory relief was not necessary or proper due to the absence of a justiciable controversy. If OEHHA had done so, this would have alerted Baxter that it needed to expand on its assertion that it sought declaratory relief because it was being required to choose between giving an unwarranted stigmatizing Proposition 65 warning or taking the risk of subjecting itself to enforcement actions.

penalty, is involved. This argument misunderstands who has the burden of proof on appeal. It is OEHHA's burden to demonstrate error; therefore, it must show that the rationale in *Zeitlin* does not apply with respect to statutes imposing civil penalties. OEHHA has not done so. It merely relies on *City of Santa Rosa v. Press Democrat* (1986) 187 Cal.App.3d 1315 (hereafter *City of Santa Rosa*) for the proposition that making a decision based on the law involves risk, and the fact the choice posed by a civil law creates a dilemma, does not give rise to a right to declaratory relief. But *City of Santa Rosa*, like *Filarsky*, involved the CPRA; and the result was premised on the fact the pertinent statute did not permit the government agency to obtain declaratory relief despite its desire for certainty. Thus, *City of Santa Rosa* is inapposite.

OEHHA also relies on *City of Santa Rosa, supra*, 187 Cal.App.3d at page 1323, for the proposition that declaratory relief is not available where there is no pending or threatened enforcement action against the party seeking declaratory relief. But the threat of an enforcement action is not just a hypothetical in the present case, given the superior court's observation that two such actions had been filed against Baxter.

In addition, OEHHA argues that declaratory relief was not necessary or proper because Baxter had another remedy; it could litigate the application and scope of the exemption exposure as a defense in the enforcement actions. However, it is only where an alternative remedy offers more effective relief, or is as well suited to the plaintiff's needs as is declaratory relief, that the court is justified in refusing a declaration because of the

availability of another remedy. (*Jones v. Robertson* (1947) 79 Cal.App.2d 813, 820.)

Requiring Baxter to litigate the exemption as a defense in an enforcement action is not a more effective remedy because this would not provide Baxter with global relief concerning all of its products. Instead, it would establish only that Baxter need not provide a warning with respect to the particular product involved in the enforcement action. Baxter could be subjected to multiple enforcement actions given that it produces more than one medical product containing DEHP. Declaratory relief is appropriate in order to avoid a multiplicity of actions. (*Californians for Native Salmon, supra*, 221 Cal.App.3d at p. 1430.)

V

We next consider Baxter's burden of proof to establish that exposure to DEHP presented no significant risk of cancer in humans. OEHHA contends the superior court erred in applying the preponderance of the evidence standard rather than requiring proof by clear and convincing evidence. The contention fails.

Evidence Code section 115 states in pertinent part: "Except as otherwise provided by law, the burden of proof requires proof by a preponderance of the evidence." The "law" referred to in Evidence Code section 115 is not limited to statutory law; it includes constitutional and decisional law. (Evid. Code, § 160.) Therefore, "[t]he default standard of proof in civil cases is the preponderance of the evidence," unless otherwise indicated by constitutional, statutory, or decisional laws. (*Conservatorship of Wendland* (2001) 26 Cal.4th 519, 546.)

Nothing in Proposition 65 dictates that a warning exemption must be proved by clear and convincing evidence, and OEHHA points to no decisional or constitutional authority directing that the burden of proof is by clear and convincing evidence. OEHHA simply argues that policy considerations regarding the protection of the public's health weigh in favor of a clear and convincing standard of proof. We are not persuaded.

"The degree of burden of proof applied in a particular situation is an expression of the degree of confidence society wishes to require of the resolution of a question of fact. [Citation.] The burden of proof thus serves to allocate the risk of error between the parties, and varies in proportion to the gravity of the consequences of an erroneous resolution. [Citations.] Preponderance of the evidence results in the roughly equal sharing of the risk of error. [Citation.] To impose any higher burden of proof demonstrates a preference for one side's interests. [Citation.]" (*In re Marriage of Peters* (1997) 52 Cal.App.4th 1487, 1490; see also *Conservatorship of Wendland*, *supra*, 26 Cal.4th at p. 546.)

The determination of the degree of proof to be applied in a particular situation "has traditionally been left to the judiciary to resolve" based on the rights and interests at stake. (*In re Marriage of Peters*, *supra*, 52 Cal.App.4th at p. 1490.) Generally, a higher burden of proof applies only where particularly important individual interests or rights, which are more substantial than the loss of money, are at stake. (*Id.* at pp. 1490-1491; *Conservatorship of Wendland*, *supra*, 26 Cal.4th at p. 546.) Thus, for example, the

clear and convincing evidence burden of proof has been applied where constitutional due process rights or important general public policy considerations are implicated. (See 1 Witkin, Cal. Evidence (4th ed. 2000) Burden of Proof and Presumptions, § 39, pp. 188-190, and cases cited therein.)

OEHHA argues that a wrong decision regarding the application of an exposure exemption is much more serious than an erroneous decision in an ordinary suit for money damages because it could result in people being exposed unknowingly to a substance that may cause cancer in humans, and the lack of warning would preclude their ability to take steps to protect themselves or to avoid exposure.

The superior court acknowledged the importance of the protective function of Proposition 65, which declares the people's right to protect themselves against chemicals that cause cancer.<sup>6</sup> However, the court noted that Proposition 65 is not an entirely

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<sup>6</sup> Section 1 of Initiative Measure, Proposition 65, provides: "The people of California find that hazardous chemicals pose a serious potential threat to their health and well-being, that state government agencies have failed to provide them with adequate protection, and that these failures have been serious enough to lead to investigations by federal agencies of the administration of California's toxic protection programs. The people therefore declare their rights: [¶] (a) To protect themselves and the water they drink against chemicals that cause cancer, birth defects, or other reproductive harm. [¶] (b) To be informed about exposures to chemicals that cause cancer, birth defects, or other reproductive harm. [¶] (c) To secure strict enforcement of the laws controlling hazardous chemicals and deter actions that threaten public health and safety." (See Historical and Statutory Notes, 40C West's Ann. Health & Saf. Code (1999 ed.) foll. § 25249.5, p. 279.)

one-sided public protection statute. The Act recognizes the interests of manufacturers and the users of needed chemicals in that it does not forbid the use of chemicals known to cause cancer; it only requires that the public be warned of potential exposure to the chemicals. (§ 25249.6.) Even then, the Act provides that the warning requirement "shall not apply" during the first 12 months after the chemical is listed. (§ 25249.10, subd. (b).) And Proposition 65 expressly states that warnings need not be given at all when there is no significant risk of developing cancer from the exposure. (§§ 25249.6, 25249.10, subd. (c).)

Thus, the superior court concluded that to impose a standard of proof higher than preponderance of the evidence "would be to tip the statutory balancing of interests even further in favor of the public than the statutes do themselves," and that if this had been the initiative's intent, its drafters would have written the higher standard of proof into Proposition 65. We agree.

Before a chemical may be listed, it must be "clearly shown" to cause cancer, or an authoritative body must have formally identified the chemical as causing cancer. (§ 25249.8, subd. (b).) Yet the warning exemption does not similarly require it to be clearly shown that exposure to the chemical poses no significant risk of causing cancer. (§ 25249.10, subd. (c).) This indicates the burden of proving the exemption is less than by clear and convincing evidence. (*In re Marquis D.* (1995) 38 Cal.App.4th 1813, 1827 [where a statute on a particular subject requires clear and convincing proof and a related statute is silent regarding the burden of proof, this can be an indication that only a preponderance of the evidence

standard is required by the related statute]; *In re Gerald J.* (1991) 1 Cal.App.4th 1180, 1186 [where one statute omits a particular provision, then the inclusion of that provision in another related statute indicates an intent that the provision is not applicable to the statute from which it was omitted].)

Furthermore, requiring a business to prove the application of the warning exemption by clear and convincing evidence in an enforcement action would be inappropriate because (1) there is no indication in Proposition 65 that the plaintiff must prove a violation of the Act by anything other than a preponderance of the evidence, as is typically the case in proving violations of public health and safety statutes (see, e.g., *Aguilar v. Atlantic Richfield Co.* (2001) 25 Cal.4th 826, 866 [unfair competition law]; *Schreidel v. American Honda Motor Co.* (1995) 34 Cal.App.4th 1242, 1250-1251 [Song-Beverly Consumer Warranty Act]), and (2) there is no indication in Proposition 65 of an intent to impose a disparate burden of proof on parties to enforcement actions. (Compare Gov. Code, § 19702, subd. (j) [expressly stating a plaintiff need only prove by a preponderance of the evidence that his or her opposition to an unlawful employment practice was a contributing factor in an adverse employment action taken against the plaintiff, but the defendant employer must show by clear and convincing evidence that the employment action would have been taken regardless of the person's protected activities].) There is no reason for applying a different burden of proving the exemption in an enforcement action, than in a declaratory relief action.

OEHHA's argument that a clear and convincing standard is appropriate because of "the dire consequences that would result from an erroneous determination" presupposes that the listing of a chemical necessarily means that exposure to the chemical poses a significant risk of causing cancer in humans. But chemicals can be listed based solely on evidence that they cause cancer in animals, without any proof that they cause cancer in humans. Consequently, a failure to prove that exposure to a chemical poses no significant risk of causing cancer in humans does not necessarily mean the reverse, i.e., it does not necessarily mean there is a significant risk the chemical causes cancer in humans. It only means the person relying on the exemption does not have enough proof to definitively establish a negative. Under the circumstances, requiring proof of the exemption by a preponderance of the evidence does not pose as dire a threat to the public health as posited by OEHHA.

In sum, the concerns represented by the warning requirement of Proposition 65, and the statutory exemption therefrom, are not comparable to the constitutional due process rights and public policy considerations in which the clear and convincing burden of proof has been applied. In the latter cases, an erroneous determination would mean that a person actually loses his or her liberty, citizenship, significant property rights, or other rights of a substantial magnitude. In contrast, an erroneous determination that a chemical poses "no significant risk" means that exposure warnings need not be given, not that exposure to the chemical ineluctably will lead to the development of cancer in humans. On the other hand, a wrong decision that a chemical

does pose a substantial risk of causing cancer in humans may result in serious negative consequences to those who forgo using a beneficial product, like the medical supplies manufactured by Baxter, because the product contains an unjustified warning that its use may cause cancer.

The superior court did not err in applying the preponderance of the evidence standard as required by Evidence Code section 115 unless otherwise indicated by constitutional, statutory, or decisional laws.

## VI

Lastly, OEHHA contends the superior court's judgment is not supported by substantial evidence because Baxter failed to prove by even a preponderance of the evidence that DEHP does not cause cancer in humans. Specifically, OEHHA argues the judgment is unsupported because (1) organs other than the liver might develop cancer, and Baxter's proof was limited to showing DEHP cannot cause liver cancer, and (2) Baxter failed to prove that the mechanism of PPAR $\alpha$ -mediated cell changes is the only mechanism by which DEHP can cause cancer.<sup>7</sup>

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<sup>7</sup> Baxter argues that OEHHA has waived its challenge to the sufficiency of the evidence because it failed to include the written testimony of two of Baxter's experts, Dr. Buffler and Dr. Ward, in the appellant's appendix in lieu of a clerk's transcript. However, California Rules of Court, rule 5.1(b)(5) provides: "All exhibits admitted in evidence or refused are deemed part of the appendix, whether or not it contains copies of them." The record discloses that the doctors' written testimony was admitted in the form of exhibits in the superior court. Hence, Baxter may not complain that OEHHA failed to provide a complete record.

Where the appellant challenges the sufficiency of the evidence, the reviewing court must start with the presumption that the record contains evidence sufficient to support the judgment; it is the appellant's burden to demonstrate otherwise. (*Foreman & Clark Corp. v. Fallon* (1971) 3 Cal.3d 875, 881.) The appellant's brief must set forth all of the material evidence bearing on the issue, not merely the evidence favorable to the appellant, and it also must show how the evidence does not sustain the challenged finding. (*Foreman & Clark Corp. v. Fallon, supra*, 3 Cal.3d at p. 881; *Niederer v. Ferreira* (1987) 189 Cal.App.3d 1485, 1510.) And the appellant must support all of its factual assertions with citations to evidence in the appellate record. (*Duarte v. Chino Community Hospital* (1999) 72 Cal.App.4th 849, 856; Cal. Rules of Court, rule 14(a).) If the appellant fails to set forth all of the material evidence, its claim of insufficiency of the evidence is waived. (*Foreman & Clark Corp. v. Fallon, supra*, 3 Cal.3d at p. 881; *Niederer v. Ferreira, supra*, 189 Cal.App.3d at p. 1510.)

In reviewing the sufficiency of the evidence, we must consider all of the evidence in the light most favorable to the prevailing party, accept as true all the evidence and reasonable inferences therefrom that tend to establish the correctness of the trial court's findings and decision, and resolve every conflict in favor of the judgment. (*Howard v. Owens Corning* (1999) 72 Cal.App.4th 621, 630-631.) "It is not our task to weigh conflicts and disputes in the evidence; that is the province of the trier of fact. Our authority begins and ends with a determination as to whether, on

the entire record, there is *any* substantial evidence, contradicted or uncontradicted, in support of the judgment." (*Ibid.*)

"We emphasize that the test is *not* the presence or absence of a substantial conflict in the evidence. Rather, it is simply whether there is substantial evidence in favor of the respondent. If this 'substantial' evidence is present, no matter how slight it may appear in comparison with the contradictory evidence, the judgment must be upheld." (*Howard v. Owens Corning, supra*, 72 Cal.App.4th at pp. 630-631; see also 9 Witkin, Cal. Procedure (4th ed. 1997) Appeal, § 364, p. 414.)

A

OEHHA claims there is no substantial evidence that the liver is the only organ which can develop cancer as the result of DEHP exposure. Therefore, according to OEHHA, it was not enough for Baxter to prove DEHP *does not cause liver cancer* in humans; rather, it had to prove that DEHP *does not cause cancer of any kind* in humans since the listing of DEHP is not limited to liver cancer. There are several problems with this contention.

First, OEHHA misperceives what Baxter was required to prove. Baxter did not have to prove that DEHP definitively does not cause cancer, only that it does not pose a *significant risk* of causing cancer. This is an important distinction.

Second, OEHHA neglects to provide a reasoned discussion of all of the evidence, which includes Baxter's evidence. It argues that "even after . . . nine days of testimony and thousands of pages of documents, there is no substantial evidence to support the trial court's judgment in favor of Baxter." But despite this

acknowledgement of the voluminous amount of evidence presented regarding DEHP's role or lack thereof in causing cancer in humans, which is an intricate and complex scientific issue, OEHHA fails to discuss the majority of the evidence in its appellate challenge.

Rather than analyzing Baxter's evidence and demonstrating it was limited to proving that DEHP does not pose a significant risk of causing *liver* cancer in humans, OEHHA simply claims Baxter "apparently assumed that it only need prove that DEHP cannot cause human liver cancer," and provides citations to nine pages in the record to support this claim. However, viewed in the light most favorable to the judgment, the cited evidence does not support OEHHA's factual assertion. It merely reflects expert testimony regarding whether DEHP is likely to cause liver cancer in humans, not evidence establishing that Baxter refused to consider or address whether DEHP posed a significant risk of causing other types of cancer in humans. Furthermore, OEHHA ignores the testimony of Baxter's experts, who opined that DEHP does not pose a significant risk of causing cancer in humans, and fails to provide any analysis demonstrating that those experts were limiting their opinions to the occurrence of liver cancer.

Because OEHHA has not set forth all of the material evidence bearing on the issue and has not affirmatively shown why that evidence is insufficient, OEHHA has waived its claim that the judgment is not supported by substantial evidence. (*Foreman & Clark Corp. v. Fallon, supra*, 3 Cal.3d at p. 881; *Niederer v. Ferreira, supra*, 189 Cal.App.3d at p. 1510.)

In any event, as we will explain, OEHHA's challenge to the sufficiency of the evidence is not persuasive, even if Baxter only proved that DEHP does not pose a significant risk of causing liver cancer in humans.

First, only chemicals "known to the state to cause cancer" are listed under Proposition 65, not chemicals for which there is a mere possibility or suspicion they will cause cancer. (*AFL-CIO v. Deukmejian, supra*, 212 Cal.App.3d at pp. 436-437.) OEHHA points to nothing in the appellate record indicating that DEHP is listed for any reason other than that it is known to cause liver cancer in rats and mice.

Second, the superior court found specifically that DEHP has not been shown to cause cancer outside the liver in rodents. OEHHA does not demonstrate that this finding is unsupported by the evidence. It merely points to evidence that DEHP may cause *pre-cancerous or benign* tumors or lesions in organs other than the liver in rats and mice via the PPAR $\alpha$  mechanism, which Baxter demonstrated does not occur in humans; that peroxisome proliferators *other than DEHP* have caused cancers in other organs; and that one study "observed" increased incidences of pancreatic tumors and leukemia in rats treated with DEHP, which is not the equivalent of proof that DEHP is *known to cause cancer in these other organs*. OEHHA simply asserts its experts had not ruled out the *possibility* that DEHP could cause cancer, and claims it presented uncontroverted evidence that "other organs and other sites *may be at risk*." (Italics added.) This is insufficient to demonstrate that DEHP is known to cause, or has been shown to

cause, cancer in organs other than the liver. Consequently, it is insufficient to undermine the superior court's finding that DEHP has been shown to cause cancer only in the liver of laboratory rats and mice.

If DEHP has been shown to cause only liver cancer in rats and mice, then it logically follows that Baxter did not have to show there was no significant risk of DEHP causing innumerable other types of cancer in every conceivable part of the human body; Baxter simply had to show that exposure to DEHP did not present a significant risk of causing liver cancer in humans. If the scientific evidence demonstrated that DEHP exposure is not likely to cause humans to develop the only type of cancer DEHP is known to cause, then there is no significant risk that exposure to DEHP will cause cancer in humans.<sup>8</sup>

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<sup>8</sup> In its opening brief, OEHHA argues that (1) Baxter failed to prove it is more likely than not that DEHP does not cause cancer in *humans*, (2) Baxter was required to prove DEHP cannot cause *human* liver cancer, and (3) there is no substantial evidence to support the superior court's ruling that DEHP cannot cause *human* cancer. In its reply brief, however, OEHHA argues that proof that a chemical poses no significant risk of cancer is not limited to demonstrating that the chemical poses no significant risk of causing cancer in humans. OEHHA maintains the statute must be interpreted as requiring proof the chemical in question poses no significant risk of cancer *in either humans or animals*, which Baxter failed to do. Because this argument was raised for the first time in OEHHA's reply brief without a showing of good cause, and since OEHHA has failed to demonstrate it raised this argument in the superior court, it is waived. (*Garcia v. McCutchen* (1997) 16 Cal.4th 469, 482, fn. 10 [arguments raised for the first time in a reply brief are waived]; *Reichardt v. Hoffman* (1997) 52 Cal.App.4th 754, 764-765 [same]; *Dimmick v. Dimmick* (1962) 58 Cal.2d 417, 422 [points not urged in the trial court will not be considered for the first time on appeal];

In essence, OEHHA has attempted to escape its burden on appeal by pointing to evidence in its favor, some of which is speculative, and claiming Baxter failed to disprove it. But in order to show there is no substantial evidence to support the superior court's finding that exposure to DEHP poses *no significant risk* of cancer in humans, OEHHA must do more than rely on its own evidence indicating there is a *possibility* that cancer *might* occur in other organs in rodents, posit that it therefore *might* occur in humans, and argue that Baxter has to prove otherwise.

In sum, our review discloses that OEHHA has done nothing more than demonstrate a conflict in the experts' testimony regarding a possible risk of cancer to humans, and not a lack of substantial evidence supporting the superior court's conclusion that there is no significant risk that exposure to DEHP causes cancer in humans.

B

OEHHA also argues that substantial evidence does not support the judgment because there is no evidence that the PPAR $\alpha$ -mediated mechanism, upon which Baxter relied, is the only mechanism by which DEHP can cause cancer.

As explained previously, Baxter submitted evidence showing that DEHP induces liver cancer in rats and mice through a combination of increased cell proliferation and suppression of apoptosis. DEHP induces those effects when its metabolites enter the liver cells

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*Damiani v. Albert* (1957) 48 Cal.2d 15, 18 [same]; *Estate of Cleland* (1953) 119 Cal.App.2d 18, 21 [it is not the appellate court's responsibility to ascertain whether a party properly preserved a point in the trial court].)

and activate the PPAR $\alpha$  receptors. Activation of PPAR $\alpha$  causes the receptor complex to enter the nucleus and bind to PPRES, thereby initiating gene transcription.

According to Baxter's evidence, it is the activation of PPAR $\alpha$  that causes alteration of gene expression, which leads to increased cell proliferation, suppression of apoptosis, oxidative stress, and ultimately the development of cancer. However, multiple studies disclose that DEHP does not increase cell proliferation or suppress apoptosis in humans exposed to DEHP because humans have insufficient levels of PPAR $\alpha$  to induce the full battery of genes necessary for the induction of cancer. Furthermore, when exposed to DEHP, human PPRES do not function in the same manner as those of rodents. Therefore, the altered gene expression, which occurs in rats and mice exposed to DEHP, does not occur in humans.

The superior court found that "Baxter's experts presented a detailed, coherent and persuasive theory explaining the mechanism by which DEHP exposure leads to cancer in laboratory animals and further explaining why that mechanism does not operate in humans." It noted that although there was no uniform consensus among the scientific experts in favor of Baxter's model of carcinogenesis, the weight of scientific opinion supported Baxter's theory. The court concluded that OEHHA had not presented sufficient evidence to overcome Baxter's showing; OEHHA only demonstrated there was some degree of uncertainty regarding Baxter's proposed model of carcinogenesis.

In other words, the court found there is no significant risk that exposure to DEHP causes cancer in humans because (1) the

preponderance of the evidence supports Baxter's theory regarding the biological mechanism by which DEHP causes cancer, and (2) this mechanism does not operate in humans.

OEHHA fails to demonstrate that the court's predicate findings are unsupported by substantial evidence. It merely argues "the primary reason why Baxter's theory falls [*sic*] is that OEHHA's experts presented uncontroverted evidence that DEHP and other peroxisome proliferators *may* cause cancer and pre-cancerous effects," or "*may* cause cancer, and *may* cause effects that are on the path to cancer," through biological mechanisms that work independently of PPAR $\alpha$ . (Italics added.) But evidence that DEHP "may" cause cancer via mechanisms other than the one posited by Baxter does not undermine the court's finding that the weight of the evidence demonstrates otherwise.

In effect, OEHHA is asking us to (1) reweigh the evidence, (2) conclude that DEHP exposure necessarily poses a *significant risk* of causing cancer in humans because there is a *possibility* that it can cause cancer in ways other than the one demonstrated by Baxter, and (3) reverse the judgment based on a mere conflict in the evidence. When viewed in this light, it is readily apparent OEHHA has failed to meet its burden of showing there is no substantial evidence to support the superior court's judgment.

DISPOSITION

The judgment is affirmed. The parties shall bear their own costs on appeal. (Cal. Rules of Court, rule 27(a).)

\_\_\_\_\_ SCOTLAND \_\_\_\_\_, P.J.

We concur:

\_\_\_\_\_ NICHOLSON \_\_\_\_\_, J.

\_\_\_\_\_ RAYE \_\_\_\_\_, J.