COMMENTS

of

THE WASHINGTON LEGAL FOUNDATION

to the

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

Concerning

Proposed Repeal of Article 6 and Adoption of New Article 6 in Title 27, California Code of Regulations ("Clear and Reasonable" Warnings)

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Via Electronic Mail
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Ms. Monet Vela
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P.O. Box 4010
Sacramento, CA 95812-4010

RE: Clear and Reasonable Warnings Regulations

Dear Ms. Vela:

Pursuant to the January 16, 2015 public notice of proposed rulemaking, the Washington Legal Foundation (WLF) hereby submits these comments to the Office of Environmental Health Hazard Assessment (OEHHA) on its proposed repeal of Article 6 and adoption of a new Article 6 in the Safe Drinking Water and Toxic Enforcement Act of 1986, codified at Title 27, California Code of Regulations (commonly known as Prop 65).

In its notice of proposed rulemaking, OEHHA announced that the proposed amendments were "intended to implement the Administration's visions concerning the quality of warnings and to provide certainty for businesses subject to" Prop 65. While WLF certainly agrees that many aspects of Prop 65 must be reformed in order to improve the business climate in the State of California, WLF fears that the proposed amendments—as currently written—will do *nothing* to address the chief regulatory burdens and abuses arising from Prop 65. In particular, OEHHA's proposed requirement that up to 12 specific chemicals be listed on all "clear and reasonable" warnings represents a significant departure from longstanding Prop 65 policy of providing a generic safe harbor. As explained in more detail below, this new requirement would burden businesses not only with the need to identify consumers' potential exposure to each specific component or ingredient offered in the company's products and services, but with a markedly increased risk of frivolous litigation if they fail to do so.

Interests of WLF

Founded in 1977, Washington Legal Foundation is a public-interest law firm and policy center based in Washington, D.C. with supporters throughout the United States. WLF devotes a substantial portion of its resources to defending and promoting free enterprise, individual rights, a limited and accountable government, and the rule of law. To that end, WLF regularly opposes the imposition of unduly burdensome regulatory labeling on the business community, at both the state and federal level, and supports the right of companies to advertise and provide consumers with truthful information about their products. *See, e.g., R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012). Most recently, WLF filed comments with Vermont's Attorney General, urging him to substantially revise his proposed regulations implementing Act 120, Vermont's law requiring foods containing genetically modified (GM) ingredients to include GM labeling. *See* WLF Comments, *Consumer Protection Rule 121—Labeling Foods Produced With Genetic Engineering* (February 12, 2015). WLF also filed comments last year with the FDA, reminding the agency that its proposed revisions to nutrition labeling requirements must comply with the First Amendment. *See* WLF Comments, *Proposed Revisions of the Nutrition and Supplemental Facts Label* (August 1, 2014).

In addition, WLF's Legal Studies Division, the publishing arm of WLF, frequently produces and distributes articles on a wide array of legal issues related to warning labels, including those arising from California's Proposition 65 law ("Prop 65"). *See, e.g.*, Lisa L. Halko, *California Court Reluctantly Rejects Proposition 65 Appeal*, WLF LEGAL BACKGROUNDER (Mar. 27, 2009); Ann G. Grimaldi, *Manufacturer's Lawsuit Spotlights Substance Listings Under Proposition 65*, WLF LEGAL BACKGROUNDER (Nov. 30, 2007); Andrea D. Tiglio, *Court Should Dismiss Junk Science-Based Proposition 65 Suit*, WLF LEGAL OPINION LETTER (Jan. 12, 2007); Thomas H. Clarke, Jr., *An Exaggerated and Ill-Conceived Sense of Risk: The Ephemeral Nature of California's Proposition 65*, WLF WORKING PAPER (April 2006).

Proposed Amendments for "Clear and Reasonable" Warnings

Adopted by California voters as an initiative measure in 1986, Prop 65 provides that "[n]o person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual, except as provided in Section 25249.10 [of the Health and Safety Code]." Cal. Health & Safety Code,

§ 25249.6.[1] The Governor of California is required to maintain a list of chemicals "known by the state" to cause cancer or reproductive toxicity. Cal. Health & Safety Code, § 25249.8.

Since Prop 65's enactment, a business whose products contain any detectable amount of one of more than 900 chemicals can face enforcement lawsuits brought by for-profit "bounty hunter" plaintiffs. Current Prop 65 regulations allow a business to immunize itself from such bounty hunter suits by providing a safe harbor for any business that labels or displays its products with a simple, one-sentence, black-on-white "clear and reasonable" warning (in English): "This product contains chemicals known to the State of California to cause cancer, birth defects, or other reproductive harm." Under the current regulatory regime, this warning constitutes *per se* compliance with Prop 65, and no specific chemical(s) (or any other information) need be disclosed to fall within the regulatory safe harbor.

On January 12, 2015, the OEHHA proposed extensive amendments to the regulations implementing Prop 65's requirement that warnings be sufficiently "clear and reasonable" to qualify for the safe harbor. Whereas the existing "clear and reasonable" requirement does not require a Prop 65 warning to name specific chemicals (except for warnings on alcoholic beverages), the proposed revisions would require most such warnings to list up to 12 specific chemicals: (1) Acrylamide, (2) Arsenic, (3) Benzene, (4) Cadmium, (5) Carbon Monoxide, (6) Chlorinated Tris, (7) Formaldehyde, (8) Hexavalent Chromium, (9) Lead, (10) Mercury, (11) Methyl Chloride, and (12) Phthalates.

Moreover, the proposed warning must be accompanied by a yellow triangle pictogram containing an exclamation point (!) and, instead of stating that a product merely "contains" a chemical or chemicals, must explicitly inform the reader that a product "can expose you" to said chemical or chemicals "known to the State of California to cause cancer and birth defects or other reproductive harm." If the product label displays a foreign language for any reason (*e.g.*, in French for Canadian products or in other languages for free-trade purposes), the warning must also appear in that foreign language (in addition to English).

[1] The principal exceptions listed in § 25249.10 are that no warning is required if federal law addresses the warning issue in a manner that preempts California law, or if the business can demonstrate that the exposure "poses no significant risk" of cancer or reproductive toxicity.

In addition, the proposed amendments would require new, specialized warnings for certain types of consumer products and services, including (1) food and dietary supplements, (2) alcoholic beverages, (3) restaurant foods and non-alcoholic beverages, (4) prescription drugs, (5) dental care, (6) furniture, (7) diesel engine exhaust, (8) parking facilities, and (9) amusement parks. OEHHA also proposes more onerous and detailed warnings for "environmental exposure" in designated smoking areas, petroleum products, and automotive repair facilities.

WLF's Concerns

A principal difficulty with Prop 65 is that California has established a considerably lower threshold for determining whether a chemical causes cancer or reproductive toxicity in humans than have the federal government and other States. As a result, plaintiffs' lawyers have brought vast numbers of lawsuits over the past three decades, claiming that companies have exposed the public to dangerous chemicals without providing an adequate warning—even though there often is little or no scientific evidence that the chemical in question actually causes cancer or reproductive toxicity in humans and even though *no other government* deems such warnings necessary. These suits have been hugely expensive for the business community and have interfered with the free flow of interstate commerce, because a product destined for California ends up requiring labeling that differs from the labeling required when that same product is sold anywhere else. *See* Travis J. Burch, *Is Prop. 65 Carcinogenic to Business?*, ORANGE COUNTY LAWYER, 16-19 (January 2011).

Determining the level of chemical exposure likely from any given consumer product or service is both difficult and costly. Under the current framework, businesses are permitted to provide a general safe harbor warning on consumer products based on potential exposure to a listed chemical, without the need to assess the actual amount a consumer may be exposed to. But OEHHA's proposed amendments would take away this protection by eliminating the generic safe harbor warning in favor of new, complicated, and highly specialized warning language. In doing so, the proposed regulations would expose businesses to an even greater risk of litigation and create additional uncertainty over the adequacy of such warnings. Under the new regulation, a business could be sued for failure to include one or more listed chemicals on a warning, so long as detectable amounts of any of the 12 chemicals are present. And given advances in technology, what is detectable today is far greater than what was detectable in 1986, when Prop 65 was passed.

The vast majority of current Prop 65 litigation relates not to the content of any given warning (an issue that the proposed amendments now seek to *inject*), but rather to

whether and when a warning is required in the first place. Offering solutions to such vexing problems as how to test for compliance, what tests to apply and when, and how to interpret the test results would provide greater guidance for businesses seeking to comply fully with Prop 65. But rather than address these glaring uncertainties, the proposed amendments would only further exacerbate them and invite an avalanche of new litigation over the *content* of Prop 65 warnings. And because the proposed amendments do not grandfather in any warnings previously approved in settlements, court judgments, or otherwise, many businesses will find themselves re-litigating matters for which they already spent a significant amount of time and money to put behind them. Yet the rule of law requires governments to provide regulated entities with clear advance notice of what conduct will and will not run afoul of the law. Whatever its faults, the prior safe harbor warning at least provided the business community with much needed certainty. The new amendments, however, would significantly erode that certainty more than ever before and radically transform Prop 65 into a legal game of "gotcha."

As with so many of Prop 65's regulations, the requirement to include one or more of 12 specific chemicals on warnings is unsupported by any scientific basis. Thus, a chemical may end up being listed even if the underlying data would not support a toxicological conclusion that the chemical may pose harm to humans. Chemicals on the "dirty dozen" list range from those so demonstrably toxic they are certain to harm humans (arsenic) to those that most Americans come into contact with every day (phthalates). One has to question whether all twelve of these chemicals should be treated the same when the level of risk associated with them is so clearly variable.

Likewise, it is generally undisputed among scientists that it is the *amount* of the chemical received by an individual that is the predominate factor in determining whether the exposure will have adverse effects on the individual's health. Large doses of chemicals such as carbon monoxide can be lethal, whereas small doses produce *no* toxic effects whatsoever. So too, an extremely high dose of even something as innocuous as pure drinking water can be lethal in high enough quantities. Nevertheless, essentially the same message of *harm* is required by the proposed amendments, regardless of the chemical and regardless of the amount. The only basis offered by OEHHA for the new rule is that the 12 chemicals are "commonly found in household products, including foods," are "commonly understood," and "easy to pronounce." (One might readily question just how easy it is to properly pronounce "phthalates"). Absent any scientific basis, however, the proposed requirement unjustifiably elevates the perceived significance of certain chemicals in the eyes of the public.

WLF also has concerns about the lack of any objective, scientific basis for OEHHA's proposed changes to the form and appearance of the warnings themselves. To

date, the agency has provided no empirical research, peer-reviewed or otherwise, demonstrating that more detailed and specialized warnings, including a yellow pictogram with an exclamation point, will somehow better inform consumers or result in less exposure to the listed chemicals. Nor has OEHHA indicated that it intends to conduct such studies. Rather, at an April 14, 2014 working session, OEHHA indicated that the current changes are based, in large measure, on phone calls to the agency. WLF believes that OEHHA should not impose burdensome compliance costs and an increased threat of litigation on businesses without fact-based evidence of a benefit to consumers (who will doubtlessly pay more for goods and services as these testing, labeling, and paperwork costs are passed on).

Finally, the proposed amendments make no mention of the First Amendment. WLF finds that omission quite surprising given the significant constraints the First Amendment imposes on the authority of California or any other government to compel speech. Both the right to speak and the right to refrain from speaking are "'complementary components of the broader concept of individual freedom of mind' protected by the First Amendment." *R.J. Reynolds*, 696 F.3d at 1211 (quoting *Wooley v. Maynard*, 430 U.S. 705, 714 (1977)). As the D.C. Circuit has recently explained, government efforts to compel speech are generally subject to "strict scrutiny," and "[t]he general rule 'that the speaker has the right to tailor the speech[ ] applies not only to expressions of value, opinion, or endorsement, but equally to statements of fact the speaker would rather avoid.'" *Id*. (quoting *Hurley v. Irish-Am. Gay, Lesbian & Bisexual Grp. of Boston*, 515 U.S. 557, 573-74 (1995)). Such First Amendment constraints against compelled speech apply just as fully to corporations as they do to individuals. *Id*. In light of those constraints, it is essential that any government agency charged with implementing a speech-compelling statute (such as Prop 65) carefully tailor its regulations to ensure that any interference with speech rights is kept to a bare minimum. OEHHA has failed to do so, and that failure may well make the entire Prop 65 regulatory regime ripe for First Amendment challenge. Even under the somewhat "deferential" standard of review articulated by the Supreme Court in *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 616 (1985), regulatory warning labels must be limited to purely "factual and uncontroversial information directed toward preventing consumer deception." 471 U.S. at 651. It is hardly "factual" or "uncontroversial" to compel businesses to label products as containing chemicals that cause cancer when they in point of fact are *not* known to cause cancer at the levels to which someone consuming or using the product is likely to be exposed.

Conclusion

WLF appreciates the opportunity to share its views on the proposed amendments to the "clear and reasonable" warning provisions implementing Prop 65. OEHHA's

proposed amendments are highly problematic because they would eliminate a business's ability to simply and cleanly satisfy the requirements of the statute through use of a generic "safe harbor" warning. In its stead, OEHHA proposes a complicated, controversial, and burdensome warning regime that must be tailored to specific circumstances, all without offering any scientific basis for doing so. By compelling such speech in violation of the First Amendment, the State of California is courting legal action to overturn Prop 65 on federal constitutional grounds. WLF urges OEHHA to withdraw the proposed amendments in their entirety.

Respectfully submitted,

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