



CALIFORNIA'S PROP. 65 AT A CROSSROADS: WILL COURTS DEMAND MISLEADING CANCER WARNINGS OR END OVER-WARNING?

by Victor E. Schwartz and Cary Silverman

Two California courts are in the midst of deciding whether consumers must be warned that everyday items that they eat, drink, and use are “known to cause cancer,” when science indicates that these products are safe and may even have health benefits. The outcome of this litigation will shape whether California’s “right to know” law, commonly known as Proposition 65 (Prop. 65), is applied to provide scientifically-backed warnings of actual health risks to consumers as intended, or overused by plaintiffs’ attorneys and advocacy groups to generate lawsuits and compel labeling and signage that scares consumers away from safe products and hurts the effectiveness of warnings of real dangers.

The rulings pose a stark contrast on that key issue. In February, U.S. District Court Judge William Shubb of the Eastern District of California entered a preliminary injunction that prohibits California from requiring companies whose products include a detectable level of glyphosate, an herbicide widely used in agriculture that can be present in foods, to label these products as causing cancer. *Nat’l Ass’n of Wheat Growers v. Zeise*, No. 2:17-2401, 2018 WL 1071168 (E.D. Cal. Feb. 26, 2018). The following month, however, California Superior Court Judge Elihu M. Berle found that companies that sell coffee—from Starbucks to Kraft—failed to meet their burden under Prop. 65 of proving that coffee does not require a cancer warning. *Council for Educ. & Research on Toxics v. Starbucks Corp.*, No. BC435759, 2018 WL 1678204 (Cal. Super. Ct., Los Angeles County, Mar. 28, 2018). There will be significant developments in these cases in the months ahead.

California’s Proposition 65

Thirty-plus years ago, California voters approved the “Safe Drinking Water and Toxic Enforcement Act,” a law intended to provide residents with information about compounds in the environment around them that might be harmful. The crux of Prop. 65 is one sentence, instructing that “[n]o 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.” CAL. HEALTH & SAFETY CODE § 25249.6.

To implement this requirement, California’s Office of Environmental Health Hazard Assessment (OEHHA) compiles a list of chemicals that are viewed as probable carcinogens. It can add chemicals to this list based on an assessment by the state’s own experts or if a state or federal agency has formally required the chemical to be labeled as causing cancer or reproductive toxicity. *Id.* § 25249.8(b). More commonly, however, chemicals are added to the list based on a finding by a “body considered to be authoritative” by the

Victor E. Schwartz and **Cary Silverman** are Partners in Shook, Hardy & Bacon LLP’s Washington, DC-based Public Policy Group. The views expressed in this backgrounder are the views of the authors and do not necessarily reflect those of the firm or its clients.

state's experts or by the International Agency for Research on Cancer (IARC). *Ibid*; CAL. LABOR CODE § 6382(b) (1), (d). Over time, California's list of cancer-causing chemicals has grown to twenty-two pages. If a product has even a trace amount of one of the nearly one thousand substances on that list, the seller must label it as "known to cause cancer" unless it is prepared to defend its doing otherwise in a lawsuit seeking substantial civil penalties (up to \$2,500 per day per violation). CAL. HEALTH & SAFETY CODE § 25249.7(b).

The California law can be enforced by the state's attorney general and local prosecutors. Most enforcement actions, however, originate through a bounty-hunter provision under which private plaintiffs and their lawyers serve as private attorneys general. The law entitles plaintiffs to twenty-five percent of the civil penalties collected as well as their attorneys' fees. *Id.* § 25249.12(d); CAL. CIV. PROC. CODE § 1021.5. As a result, Prop. 65 has created a cottage litigation industry. Companies protect themselves by conveying warnings regardless of whether a true risk of cancer or reproductive toxicity is backed by sound science. They often quickly settle claims and pay a penalty and attorneys' fees. In 2017, companies settled 688 Prop. 65 cases with 24 advocacy groups, law firms, and individuals, including \$25.8 million in settlement payments. More than three-quarters of this sum went to their lawyers.¹ Private enforcers sent 2,710 violation notices to businesses in 2017 and about 800 of these demand letters in 2018 through May.²

The American Cancer Society has issued its own warnings about Prop. 65. Its website instructs consumers concerned by Prop. 65 warnings that some of the chemicals on the list are known to cause cancer, others might cause cancer, and still others have not been proven to the worldwide scientific community as actually causing cancer. The ACS cautions: "The Prop 65 labels only tell you that a product has something in it that might cause cancer or affect reproduction. They don't say what the substance is, where it is in the product, how you might be exposed to it, what the level of risk is, or how to reduce your exposure."³

Federal Court Enters Preliminary Injunction, Finding Glyphosate Cancer Warning "Misleading at Best"

In late 2015, OEHHA initiated the process for listing glyphosate as a chemical known to California as causing cancer. It did so soon after a panel of scientists hand-picked by IARC classified glyphosate as "probably carcinogenic" to humans. OEHHA added glyphosate to its list of chemicals requiring a Prop. 65 cancer warning on July 7, 2017, with the warning requirement set to take effect one year later. Before that occurred, a coalition of associations representing agricultural and business interests filed a lawsuit in federal court to block implementation of this mandate. The groups alleged that requiring products that include glyphosate to be labeled "known to the state of California to cause cancer" or "known to cause cancer" violates the First Amendment by compelling them to make statements about their products that are false, misleading, and controversial. *Nat'l Ass'n of Wheat Growers*, 2018 WL 1071168, at *6.

Judge Shubb agreed. "A reasonable consumer," the court found, "would not understand that a substance is 'known to cause cancer' where only one health organization has found that the substance in question causes cancer and virtually all other government agencies and health organizations had found no evidence that it caused cancer." *Ibid*. The EPA, the court observed, had repeatedly found no or insufficient evidence that glyphosate causes cancer and several international agencies had reached the same conclusion. Given the "heavy weight" of the scientific evidence, it is "inherently misleading," the court found, to require a warning stating that any product that includes glyphosate is "known to cause cancer," when it is not. *Ibid*.

¹ State of California Dep't of Justice, Proposition 65 Settlement Summary 2017, <https://oag.ca.gov/sites/all/files/agweb/pdfs/prop65/2017-summary-settlements.pdf>.

² See State of California Dep't of Justice, 60-Day Notice Search, <https://www.oag.ca.gov/prop65/60-day-notice-search>.

³ Am. Cancer Society, Cancer Warning Labels Based on California's Proposition 65, <https://www.cancer.org/cancer/causes/general-info/cancer-warning-labels-based-on-californias-proposition-65.html>.

The court rejected a nuanced interpretation offered by the state that the mandated label would be “literally true” since California lists the substance as causing cancer, per Prop. 65. “[T]he most obvious reading of the Proposition 65 warning is that exposure to glyphosate in fact causes cancer,” the court ruled. *Ibid.* Conveying misleading labels to consumers undermines the state’s interest in accurately informing citizens of health risks, Judge Shubb found. *Id.* at *8.

On March 26, 2018, California Attorney General Xavier Becerra asked the court to alter or amend its judgment, characterizing the lack of scientific support for the classification aside from the IARC finding as a “scientific disagreement [that] does not justify suppressing truthful information.” If the court continues to find the mandated warnings misleading, the attorney general suggests two alternatives. The first option, which the state presents as “purely factual,” would require companies to warn that glyphosate is “listed as causing cancer pursuant to the requirements as California law.” As the court found in issuing the injunction, however, this nuance is likely to be lost on consumers. The second option would tell consumers glyphosate is “listed as causing cancer” by IARC, but indicate that the EPA has found otherwise. While this option recognizes a disagreement, it appears to continue to misrepresent what the court found was the “great weight” of the scientific evidence. The court has scheduled a hearing on the motion on June 11, 2018.

California State Court Moves toward Requiring Cancer Warnings on Coffee

Judge Shubb’s ruling with respect to glyphosate warnings stands in stark contrast to a ruling by Judge Berle, which has cleared the way toward requiring every company that sells coffee in California to warn consumers that their morning brew is known to cause cancer.

The Prop. 65 coffee litigation has been ongoing for eight years. Brought by the Council for Education and Research on Toxics (CERT), it has grown to include ninety-one companies that sell “ready-to-drink” or packaged coffee in California. The action alleges that coffee contains acrylamide, which is listed as a carcinogen, and that coffee sellers failed to fulfill their obligation to warn consumers under Prop. 65. Coffee naturally contains trace amounts of acrylamide, which is produced when beans are roasted. Many other foods also contain acrylamide created during cooking, including potato chips, french fries, crackers, cookies, cereal, toast, prune juice, black olives, and grilled asparagus.

Unlike the usual Prop. 65 case where businesses quickly settle, pay fees, and add warnings, warranted or not, the coffee sellers went to trial. The bench trial’s first phase resulted in the court rejecting affirmative defenses based on the First Amendment and federal preemption, and finding that the companies failed to show lifetime exposure to the level of acrylamide in coffee poses no significant risk of cancer. *Council for Educ. & Research on Toxics v. Starbucks Corp.*, No. BC435759 (Cal. Super. Ct., Los Angeles County, June 26, 2015). While the companies introduced epidemiological studies in their defense, the court found they had not presented credible evidence of the degree of risk posed by acrylamide in coffee. *Id.* at 14-15. It rejected scientific evidence examining the cancer risks of coffee on the basis that the studies focused on coffee, rather than acrylamide, the substance California considers to be “known to the state to cause cancer.” *Ibid.*

As the trial proceeded into the second phase, at least thirteen coffee companies settled.⁴ 7-Eleven agreed to post signage in its California stores alerting consumers of the presence of a cancer-causing chemical in its coffee and pay \$900,000 in penalties and costs, including \$355,000 for CERT’s litigation-related costs.⁵ A BP subsidiary settled for \$675,000, including \$250,000 to CERT.⁶

⁴ Jen Christensen, *Coffee May Come With a Cancer Warning Label in California*, CNN, Mar. 30, 2018.

⁵ Melissa Daniels, *7-Eleven Settles Prop 65 Coffee Case, Will Post Signs*, LAW360, Nov. 21, 2017.

⁶ Bonnie Eslinger, *BP Unit Settles as Coffee Risk Trial Percolates*, LAW360, Sept. 6, 2017.

During the second phase of the trial, the coffee sellers had a second chance to convince the court that coffee does not cause cancer. To do so, they would need to show an “alternative level” at which chemicals produced during cooking are necessary to render the food palatable or avoid contamination and that “sound considerations of public health” support the alternative level. CAL. HEALTH & SAFETY CODE § 25703(b). In a preliminary ruling, Judge Berle again was not satisfied by the companies’ scientific evidence. *Council for Educ. & Research on Toxics*, 2018 WL 1678204, at *8-10. The court found that the companies’ experts did not calculate a precise alternative level at which acrylamide poses no significant risk of cancer. It rejected the testimony of a former FDA Commissioner indicating that a significantly higher level of acrylamide is safe based on the FDA’s regulation of carcinogens in other foods as lacking scientific support and grounded in sound considerations of public health. *Id.* at *8. Data specifically gathered on the low concentration of acrylamide in coffee was rejected as unreliably resulting from a novel and untested technique. *Id.* at *9. The court also refused to consider the testimony of three defense witnesses, finding them either unqualified or their testimony based on unreliable data. *See ibid.*

Although scientific evidence is mounting that coffee consumption may have health benefits,⁷ the court summarily rejected such studies as “not persuasive.” *Ibid.* Not mentioned in the court’s decision, for example, was that IARC removed coffee from its list of potentially carcinogenic foods in 2016, and went on to recognize coffee as potentially protective against cancer of the uterus and liver.⁸ The recent studies, contrasted with the California Superior Court’s March 2018 ruling, “left the scientific community puzzled.”⁹ After the court finalizes its ruling, the case will move into a remedies and damages phase.

Courts Should Stem Over-warning

Courts should identify and preclude warning requirements (or lawsuits alleging failure to provide a state-mandated warning) that rest on bad science or lack scientific support. Serious adverse consequences can come about when product warnings are not based on sound science. When products are engulfed with too many warnings, consumers may ignore the important ones—those that can actually help them avoid a real risk of injury. Unsupported Prop. 65 warnings, for this reason, may actually pose a danger to consumers.

With respect to glyphosate, permitting California to continue mandating deceptive, unscientifically supported warnings may lead consumers to avoid buying useful products that would do them no harm. The result would also discourage use of a safe herbicide that allows farmers to increase their yields to feed an ever-growing population. When a court demands that companies warn consumers that coffee causes cancer—despite 64% of American adults drinking coffee each day¹⁰ with no sign of a public health crisis—no warning will be taken seriously. Truly scientifically-based warnings that could avoid serious harm may be ignored because “surreal” warnings have become the judicial flavor of the day.

⁷ See, e.g., David Caplan & Olivia Myrick, *Drinking 3 to 4 Cups of Coffee a Day May have Health Benefits: Study*, ABC NEWS, Nov. 23, 2017; Daniella Emanuel, *Drinking More Coffee Leads to a Longer Life, Two Studies Say*, CNN, July 12, 2017.

⁸ See Dana Loomis et al., *Carcinogenicity of Drinking Coffee, Mate, and Very Hot Beverages*, THE LANCET ONCOLOGY, Vol. 17, No. 7, July 2016.

⁹ Soumya Karlamangla & Victoria Kim, *Go Ahead and Drink Your Coffee, Public Health Experts Say*, L.A. TIMES, Mar. 30, 2018.

¹⁰ *Americans are Drinking a Daily Cup of Coffee at the Highest Level in Six Years: Survey*, REUTERS, Mar. 17, 2018.