A Big Prop 65 Victory For Chemical Industry In Monsanto Case

By **Kendra Sherman and Danelle Gagliardi** (July 17, 2020)

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On June 22, U.S. District Judge William B. Shubb of the U.S. District Court for the Eastern District of California granted Monsanto's motion for summary judgment and imposed a permanent injunction on the enforcement of Proposition 65 for glyphosate (the active ingredient in Roundup) in the closely followed case National Association of Wheat Growers v. Becerra.

The ruling is important to many in the chemicals and agricultural world. An appeal is expected, and if the decision is upheld, it will set a significant precedent in the Prop 65 world and deal a huge blow to the state of California.

Background

The Prop 65 dispute regarding glyphosate has a history spanning around five years. In September 2015, the California Office of Environmental Health Hazard Assessment, or OEHHA, issued a notice of intent to add glyphosate to its Prop 65 list. It relied upon the Labor Code mechanism of Prop 65, where OEHHA is required to list a chemical determined to be a probable human carcinogen by the International Agency for Research on Cancer, or IARC.[1]

In March 2015, the IARC found that there was sufficient evidence from glyphosate's carcinogenic effect on animals to classify the chemical as a probable human carcinogen, and OEHHA adopted that finding to support its listing. During this time, however, the science and data surrounding whether glyphosate was carcinogenic was disputed. The U.S. Environmental Protection Agency conducted its own evaluation of glyphosate's carcinogenic potential and concluded that glyphosate was not carcinogenic. Monsanto also had internal studies based on existing research that determined glyphosate was not carcinogenic.

In January 2016, Monsanto sought an injunction in California state superior court, disputing that the chemical is dangerous and citing alternative regulatory and internal research ruling out glyphosate as a potential carcinogen. Monsanto raised a number of constitutional arguments in support of its request, including unconstitutional delegation, due process, the guarantee clause, and the First Amendment. The California superior court judge dismissed Monsanto's lawsuit, and the California Fifth District Court of Appeals affirmed in 2017.

Monsanto's argument based upon the First Amendment proved to be a winner in a subsequent federal court case brought by Monsanto after OEHHA officially listed the chemical for cancer. In February 2018, Monsanto filed a request for a preliminary injunction before the Eastern District of California, and Judge Shubb granted that injunction. He made his 2018 ruling final in June 2020 holding that labeling glyphosate products with a Prop 65 label would violate Monsanto's First Amendment rights.

First Amendment Argument

What was Monsanto's First Amendment argument? To start, California's Prop 65 requires

that a company provide a "clear and reasonable warning" on products where use can result in exposure to a listed chemical. For example, for glyphosate, such warning must state:

> WARNING: This product can expose you to chemicals including Glyphosate, which is known to the State of California to cause cancer. For more information go to www.p65warnings.ca.gov.

The key word here is "known." Monsanto argued that that listing the chemical glyphosate and compelling companies to label products by law when the science is still unknown would violate its First Amendment free speech right. Moreover, compelling such potentially false speech would mislead consumers and force Monsanto to make "highly controversial statements" on its products.

The parties in the case disputed the appropriate constitutional test for commercial speech. The state argued that the Zauderer test controlled.[2] This low scrutiny test provides that compelled commercial speech is constitutional if a company is required to assert "purely factual and uncontroversial information' about commercial products or services, as long as the disclosure requirements are 'reasonably related' to a substantial government interest and are neither 'unjustified [n]or unduly burdensome.'"[3]

Judge Shubb rejected the state's request to apply the Zauderer test, explaining that the intermediate scrutiny test set out in Central Hudson test actually controls on this "somewhat unsettled" area of law.[4] The Central Hudson test provides that "the law at issue 'must 'directly advance the governmental interest asserted' and must not be 'more extensive than is necessary to serve that interest.'"[5] Judge Shubb explained that Zauderer only controls if the statement is purely factual, and since multiple regulators, including the EPA, disagree with IARC on its conclusions regarding glyphosate, the statements are not purely factual.

In it is prior ruling on a preliminary injunction, the court recognized that "[i]t is inherently misleading for a warning to state that a chemical is known to the state of California to cause cancer based on the finding of one organization ... when apparently all other regulatory and governmental bodies have found the opposite."[6] Ultimately, Judge Shubb concluded that "misleading statements about glyphosate's carcinogenicity, and the state's knowledge of that purported carcinogenicity, do not directly advance" the state's substantial interest in providing California consumers information about exposures to chemicals that cause cancer.[7]

Ripeness

Judge Shubb also rejected the state's alternate arguments, one of which was that the claim was not ripe because Monsanto's products contained glyphosate at levels below OEHHA's set safe harbor levels (known as "no significant risk levels"). Here, the court highlighted some of the inherent problems with Prop 65 and its "cottage industry" of citizen plaintiffs' litigation:

> The fact that the statute allows any person to file an enforcement suit makes the threat of such suits more credible. ... Such suits, which can be brought notwithstanding the Attorney General's finding of no merit, are enabled by the statute itself, as defendants in Proposition 65 enforcement actions have the burden of showing that their product's glyphosate exposure falls below the no significant risk level in a Proposition 65 enforcement action.[8]

Judge Shubb determined the claim was indeed ripe because "assuming plaintiffs' products were tested and found to contain concentrations of glyphosate below the safe harbor level as set by Cal. Code. Regs. tit. 27 § 25705, plaintiffs would still have no reasonable assurance that they would not be subject to enforcement actions."[9]

Federal Agency Input

A critical aspect of this case was its emphasis on the disputed science and the involvement by the EPA. What makes this case particularly noteworthy is that the EPA was directly opposed to the state of California.

Not only had the EPA conducted its own study on glyphosate, but in August 2019 — after Monsanto had filed in federal court — the EPA penned a letter to glyphosate registrants asserting: "EPA disagrees with IARC's assessment of glyphosate." The EPA also cited the litigation and directed that "EPA will no longer approve labeling that includes the Proposition 65 warning statement for glyphosate-containing products."

Furthermore, in a parallel case, Monsanto v. Hardeman, the EPA filed an amicus brief stating that a Prop 65 warning "would be inconsistent with the agency's scientific assessments of the carcinogenic potential of the product." It also warned of preemption: "Plaintiff asserted safety labeling requirements exist under California law in addition to and different from that required, reviewed, and approved by EPA. Plaintiff is wrong and his lawyers sailed directly into preempted territory in how they opted to try this case."

We have seen federal agencies begin to display more and more interest in California's Prop 65, given its nationwide effect on commerce. For example, in Post Foods LLC v. Superior Court of Los Angeles County in 2018, the California Court of Appeal took notice of two letters issued from the U.S. Food and Drug Administration in 2003 and 2006, advising California officials that while cereal contains acrylamide, it also contains whole grains, which the FDA encourages Americans to consume.

The court ultimately determined that the federal interest the FDA has in encouraging Americans to eat more whole grains outweighed the California state-law need to warn for a potential cancer-causing chemical, noting that a Prop 65 warning for acrylamide on whole grain cereals "would mislead consumers and lead to health detriments."

Similarly, following a California superior court decision on March 28, 2018, finding that coffee required a Prop 65 warning for acrylamide, OEHHA proposed an interpretive guideline clarifying that Prop 65 cancer warnings are not required for coffee under Prop 65.[10] Interestingly, the director of the Center for Food Safety and Applied Nutrition at the FDA wrote a letter in support of the regulation:

> Simply put, if a state law purports to require food labeling to include a false or misleading statement, the FDA may decide to step in. ... The good news is that, based on this science, the California agency that administers Proposition 65 has proposed a regulation to exempt coffee from a Proposition 65 cancer warning.

The FDA coffee letter was a "warning" to the State of California. However, with the recent Monsanto decision, federal agencies may be more apt to express their opposition to certain chemical listings or product applications under Prop 65, which could lead to preemption disputes.

What's Next

The case will likely be appealed. However, for now, it sets an important precedent in the Prop 65 world.

First, it may encourage OEHHA to more heavily scrutinize the findings of IARC and available science on a chemical prior to listing it on the Prop 65 database. This will be especially true when the chemical is widely used in a particular industry, like glyphosate in the agricultural industry.

Second, the direct opposition by the EPA (and the FDA in other cases) to the state and OEHHA may foreshadow future intervention by agencies on controversial chemicals and a potential dispute regarding federal preemption.

Finally, from an industry perspective, this decision should provide some confidence to those in the regulated industry in raising constitutional arguments in Prop 65 enforcement cases. Judge Shubb made abundantly clear that Prop 65's enforcement mechanisms are severely skewed in favor of the state and citizen plaintiffs. The case is a great example of what can be achieved when an industry bands together to challenge an OEHHA decision when there are conflicting studies, science and agency opinions on the issues presented.

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[1] See Title 27, Cal.Code of Regs., section 25904.

[2] See Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio, 471 U.S. 626 (1985).

[3] See Order at p. 14.

[4] See Central Hudson Gas & Electric Corp. v. Public Service Commission, 447 U.S. 557 (1980).

[5] See Order at p. 14.

[6] Order at p. 7.

[7] See Order at p. 30.

[8] See Order at p. 10-11.

[9] See Order at p. 9.

[10] See Proposed OEHHA Regulation Clarifies that Cancer Warnings Are not Required for Coffee under Prop 65; See Council for Education and Research on Toxics v. Starbucks Corp. et al., Case No. BC435759 (California Superior Court, County of Los Angeles).