

TOXIC AND HAZARDOUS SUBSTANCES LITIGATION

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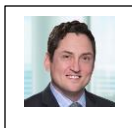
This article provides an analysis of a recent California decision granting a permanent injunction and thereby prohibiting the enforcement of Proposition 65's warning requirement for glyphosate. The decision offers a lengthy discussion and analysis of the constitutional considerations in applying the warning requirement.

Permanent Injunction Granted That Prohibits Enforcement of Proposition 65's Warning Requirement for Glyphosate

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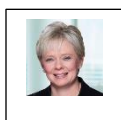
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On Monday, June 22, 2020, the United States District Court for the Eastern District of California dealt a significant blow to California's attempt to require a Proposition 65 warning for glyphosate.¹ Glyphosate is a chemical compound commonly found in popular weed killers such as Roundup that disrupts the specific enzyme pathway necessary for most plants to live.² A March 2015 International Agency for Research on Cancer (IARC) monograph classifying glyphosate as "probably carcinogenic" to humans brought it to the forefront of legal and regulatory discussions.³

In the instant case, a permanent injunction was granted whereby the defendant, the Attorney General of the State of California, was permanently enjoined from enforcing the requirement that any person in the course of doing business provide a clear and reasonable warning before exposing any individual to glyphosate. The Plaintiffs were comprised of approximately a dozen organizations, including the National Association of Wheat Growers, Missouri Chamber of Commerce and Industry and Monsanto Company (now part of Bayer AG). The rulings were issued as a result of cross motions for summary judgment on Plaintiffs' claim that Proposition 65's warning requirement, as applied to glyphosate, would violate the First Amendment.

Background

The court first addressed the background of Proposition 65, which is the "Safe Drinking Water and Toxic Enforcement Act of 1986." Part of the statute consists of the requirement that the Governor of California publish a list of chemicals known by the state to cause cancer (the "Proposition 65 List"), as determined by certain outside agencies (ex. EPA, FDA and IARC). The second part is the prohibition of any person in the course of doing business from knowingly and intentionally exposing anyone to a Proposition 65-listed chemical without a prior "clear and reasonable" warning. The court noted that there was no explanation as to what was a "clear and reasonable warning." However, California's Office of Environmental Health Hazard Assessment (OEHHA) provides "safe harbor" warnings (i.e. types of warning language considered acceptable to OEHHA) that were per se compliant.

The court then set forth the substantive and procedural history that, in 2015, the International Agency for Research on Cancer (IARC) classified glyphosate as "probably carcinogenic" to humans, and that several other organizations, including the EPA, concluded that there is insufficient or no evidence that glyphosate causes cancer. In

¹ *Natl. Assoc. of Wheat Growers v. Becerra*, No. 2:17-cv-2401 WBS EFB, 2020 WL 3412732 (E.D. Cal. June 22, 2020).

² *Questions and Answers on Glyphosate*, U.S. FOOD AND DRUG ADMINISTRATION (NOV. 13, 2019),

<https://www.fda.gov/food/pesticides/questions-and-answers-glyphosate>.

³ *IARC Monograph on Glyphosate*, INTERNATIONAL AGENCY FOR RESEARCH ON CANCER (Mar. 20, 2015), <https://www.iarc.fr/featured-news/media-centre-iarc-news-glyphosate/>.

fact, the EPA had reaffirmed its position in April 2019; and, in August 2019, stated it would not approve herbicide labels with the Proposition 65 warning, because they would be false and misleading and “misbranded” under the federal herbicide labeling law.⁴

Preliminary Injunction

Nevertheless, as a result of IARC’s classification of glyphosate as probably carcinogenic, the OEHHA put glyphosate on the Proposition 65 list on July 7, 2017, with warnings requirement to begin July 7, 2018. Initially, on February 26, 2018, the court preliminarily enjoined the warning requirement. The court believed the First Amendment challenge was considered ripe given risk of injury to the Plaintiffs, and the Proposition 65 warning was not “purely factual and uncontroversial” since it would be misleading to the ordinary consumer. The misleading concern stemmed from the language in the warning which said glyphosate was known to cause cancer; but, that conclusion was “based on the finding of one organization . . . when apparently all other regulatory and governmental bodies have found the opposite.”

The court subsequently denied the Defendant’s motion for reconsideration of the preliminary injunction. In the current matter, the Plaintiffs were now seeking a permanent injunction barring the

enforcement of the Proposition 65 warning requirement for glyphosate. However, the court was not deciding whether it was proper for glyphosate to be on the Proposition 65 list; it was to determine whether the resultant warning requirement was to be enforced.

Ripeness

The first issue the court addressed was ripeness. The analysis has both a “constitutional” and “prudential” component. The former concerns whether there is a realistic danger of injury if the statute is enforced or whether the injury is too speculative, while the latter concerns fitness of the issues and resultant hardships should the court not intervene. The case was ripe as Plaintiffs still faced a significant risk notwithstanding the assertion that no warnings would be expected due to the likelihood that glyphosate levels of Plaintiffs’ products would be below the “no significant risk level.” This risk was due to the fact that Plaintiffs could still be subject to enforcement actions, because Proposition 65 allows any person to file an enforcement suit (e.g. citizen suits), even if the Attorney General has determined that the proposed enforcement has no merit.

⁴ See *OEHHA Statement Regarding US EPA’s Press Release and Registrant Letter on Glyphosate*, CALIFORNIA OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT (Aug. 12, 2019),

<https://oehha.ca.gov/proposition-65/general-info/oehha-statement-regarding-us-epas-press-release-and-registrant-letter>.

Merit Scrutiny

The court was asked to determine the appropriate level of scrutiny – the intermediate or lower standard. Under the intermediate level, the government may restrict commercial speech that is “neither misleading or connected to unlawful activity” so long as the government interest is substantial. With respect to the lower standard, the court stated that disclosure of “purely factual and uncontroversial information” could be compelled if “reasonably related” to government interest. While there was no clear definition of “purely factual and uncontroversial information,” the court made note that the Ninth Circuit Court of Appeals explained “a statement may be literally true but nonetheless misleading and, in that sense, untrue.” The court previously found in the preliminary injunction that the Proposition 65 warning would be false and misleading “given the weight of authority showing that glyphosate was not known to cause cancer and did not cause cancer.”

While the court acknowledged some new developments since it granted the preliminary injunction, the court still opined the warning requirement for glyphosate was misleading and thus not purely factual and uncontroversial. First, despite the approved language in the available safe harbor warnings, the warnings convey that glyphosate is known to cause and actually causes cancer. Specifically, the safe harbor warning that “glyphosate is known to the State of California to cause cancer” is still

misleading as “[e]very regulator of which the court is aware, with the sole exception of IARC, has found that glyphosate does not cause cancer or that there is insufficient evidence to show that it does.” While California may technically “know” glyphosate causes cancer as the State has defined, it nevertheless would be misleading to the ordinary consumer. The court then reiterated its previous statement in granting the preliminary injunction that stated, in part,

[A] reasonable consumer would not understand that a substance is ‘known to cause cancer’ when only one health organization had found that the substance in question causes cancer and virtually all other government agencies and health organizations that have reviewed studies on the chemical had found there was no evidence that it caused cancer. Under those facts, the message that glyphosate is known to cause cancer is misleading at best.

The court determined that California could not “skew the public debate” by forcing companies to adopt the state’s determination that glyphosate is a carcinogen, relying solely in IARC’s determination, where great evidence speaks to the contrary.

The “new evidence” was then analyzed, including additional studies linking glyphosate and cancer, the California Court of Appeals decision regarding glyphosate on the Proposition 65 list, safe harbor warning

options, and three jury verdicts against Monsanto related to glyphosate. First, despite the additional cancer-linked studies and criticism of EPA findings, the studies and findings did not establish that California knows glyphosate causes cancer. Second, the ruling that glyphosate was to remain on the Proposition 65 list did not address or have any bearing on the First Amendment issue related to the warning. Third, the safe harbor warnings did not have any relevance as to whether the warning requirement was factual or uncontroversial. Fourth, the three jury verdicts against Monsanto had different questions than those before the court; and, as set forth in a footnote, those verdicts were on appeal.

The court then addressed the inadequacy of the suggested “safe harbor” warnings for glyphosate. The inadequacy was based, in part, on the fact that the safe harbor regulations prohibited certain additional information. For example, additional language discussing the debate regarding glyphosate’s carcinogenicity would not be permitted without a court order approving the language.

The court ultimately concluded warnings which stated glyphosate is known to cause cancer are not purely factual and uncontroversial, thus the Proposition 65 warning must satisfy intermediate scrutiny. The law must “directly advance the governmental interest,” but could not “be more extensive than is necessary to serve that interest.”

While the court agreed that Proposition 65’s purpose of informing Californians about exposure to the chemicals that cause cancer was a “substantial interest,” misleading statements about glyphosate’s carcinogenicity, and the state’s purported knowledge of it, did not directly advance that interest. Furthermore, California had alternate means of informing consumers that did not involve burdening businesses’ free speech, including posting on the Internet. Consequently, the warning requirement for glyphosate did not pass intermediate scrutiny under the First Amendment.

Having determined the warning requirement violated the First Amendment, the court then analyzed the appropriateness of a permanent injunction. Since there was a violation of the First Amendment, there was clearly an irreparable injury. Additionally, the balance of equities leaned in favor of Plaintiffs as opposed to the Defendant, the government, in light of the fact that California has no interest in enforcing an unconstitutional law and misleading labels actually undercuts its interest of informing consumers.

Finally, the court reached two conclusions. One, it granted Plaintiff’s motion for summary judgment with respect to Proposition 65’s warning requirement for glyphosate running afoul of the First Amendment, thus denying Defendant’s cross motion. Second, it found that a permanent injunction was appropriate.

One of the big takeaways from this decision was the degree to which the California District Court marginalized the 2015 IARC Monograph, which arguably catalyzed the entire glyphosate litigation. The Court was consistent in characterizing IARC's conclusion with respect to glyphosate's carcinogenicity as an outlier, despite the monstrous verdicts and negative media that sprung forth as a result. Indeed, the court dutifully and objectively stacked the conclusions of various agencies in two different piles, and found that the IARC conclusion had scarce company.

At this juncture, we will have to see if an appeal is filed. It will be interesting to follow how far this case goes in light of the inherent constitutional questions arising via Proposition 65's warning requirements for glyphosate.

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