Glyphosate Brief Exposes Calif.-Federal Chemical Regs Clash

By **Rebecca Lee, Christopher Smith and Mark Elliott**

Rebecca Lee

Christopher Smith

Mark Elliott

Proposition 65 is a California state regulation, unique in the 50 states, that requires a warning for exposure to one or more of the approximately 900 listed chemicals that the state has determined may cause cancer, birth defects or reproductive harm at or above certain threshold levels.

Proposition 65 has long been a source of tension between California and federal administrative agencies with jurisdiction over a variety of overlapping environmental and health and safety programs. At times, the tension can lead to changes in state law, as seen in California's recent revision of the regulations in response to U.S. Food and Drug Administration pressure to abolish Proposition 65 warnings for potential carcinogens in coffee.

After years of private party litigation over the issue, California recently amended the California Code of Regulations to align with FDA guidance and clarify that chemicals created in the roasting of coffee beans are not significantly carcinogenic.[1] This amendment reversed the state's previous requirement that coffee include a warning label, pursuant to Proposition 65, due to the presence of acrylamide in roasted coffee beans.

The dispute appears to have boiled over again in amicus curiae briefing in the case Hardeman v. Monsanto Co., pending before the U.S. Court of Appeals for the Ninth Circuit. This bellwether product liability case, which resulted in a $25 million verdict in favor of a man who claims that glyphosate — a chemical in the herbicide Roundup — caused his non-Hodgkin's lymphoma, is the latest forum for conflict between California's Proposition 65 and the Federal Insecticide, Fungicide, and Rodenticide Act, or FIFRA.

FIFRA is a federal statute that regulates the labeling, sale and use of pesticides — including herbicides like Roundup. Monsanto, the manufacturer of Roundup, contends, among other arguments, that the failure to warn tort judgment is preempted by the federal statute.

Both the state of California and the U.S. Environmental Protection Agency submitted amicus briefs. The briefs demonstrate state and federal regulators' differing views on whether FIFRA preempts Proposition 65.

While legal observers may view this lawsuit and the arguments associated with it as just the latest installment in the ongoing clash

between state and federal powers, that would be an oversimplification. This is because the recent actions taken by the EPA, seeking to effectively nullify Proposition 65's warning requirement for glyphosate, is likely to be seen as a direct affront to California's authority to regulate chemicals within the state's borders.

Disputes between California and federal powers over the application of Proposition 65 are not new.[2] Despite the number of challenges, however, Proposition 65 has largely been upheld in the face of federal preemption challenges.

Federal courts in California have generally agreed that a Proposition 65 consumer product warning will be upheld, unless all mediums by which a warning may be given conflict with federal law.[3] Proposition 65 allows exposure warnings to be placed either directly on the product or on a posted sign, shelf tag or shelf sign at the point of display of the product.[4]

The seminal case, Chemical Specialties Manufacturers Association v. Allenby, decided in 1992, reasoned that Proposition 65 point-of-sale warnings are not labels as defined by FIFRA, and therefore Proposition 65 is not preempted due to the ability to provide the warnings other than by an on-product label.[5]

However, Chemical Specialties Manufacturers Association — upon which California now relies to claim that FIFRA does not preempt Proposition 65 — was decided almost two decades before the 2016 revamp of the act's regulations. One of the hallmark changes in the 2016 revision of Proposition 65 was an emphasis that the warning responsibility for consumer product warnings should be placed on manufacturers rather than retail sellers.

By arguing to the Ninth Circuit that certain products sold in California must display mandated point-of-sale warnings rather than product labels — because manufacturers are otherwise barred from placing the warnings on-product to avoid falling afoul of FIFRA — the state is effectively reversing its own regulation in situations where on-product warnings may be preempted by federal law.

Federal Preemption and the Future of Proposition 65

Generally, federal preemption of state law occurs in one of two ways: express or implied. A federal law can expressly preempt state law when a federal statute or regulation contains explicit preemptive language.[6] This express preemptive language clearly states that federal power should not be supplemented or changed by state law.

Alternatively, a federal law can impliedly preempt state law when its structure and purpose implicitly reflect Congress's preemptive intent.[7] Within the category of implied preemption exist two subsets of implied preemption: field and conflict preemption.

Field preemption occurs when a pervasive scheme of federal regulation implicitly precludes supplementary state regulation, or when states attempt to regulate a field where there is clearly a dominant federal interest.[8] Conflict preemption occurs when compliance with both federal and state regulations is a physical impossibility, or when state law poses an obstacle to the accomplishment of the full purposes and objectives of Congress.[9]

The collision of Proposition 65 and preemption typically arises when a chemical exists in a product which triggers regulatory obligations under both Proposition 65 and a federal statute or regulation. When those regulatory obligations conflict, litigation may arise to determine whether state law is preempted by federal law. A recent example of this conflict at the state court level involves the chemical acrylamide in the 2018 case Post Foods LLC v.

Superior Court.

Acrylamide, formed in certain starchy plant-based foods during cooking, is currently listed under Proposition 65 as a carcinogen and reproductive toxicant.[10] Preemption issues arise when the labeling of a food containing acrylamide, such as a breakfast cereal, is also regulated by the FDA, which promulgates federal nutrition policies and labeling requirements.

In Post Foods, the plaintiffs alleged that, due to the presence of acrylamide in common breakfast cereals such as Frosted Flakes and Fruity Pebbles, these and nearly 60 other brands of cereal would need to display warnings that consuming the cereals could cause cancer and/or reproductive harm.

In response to the litigation, the FDA expressed concerns that attaching these warnings to cereals may scare consumers off food choices that are generally considered healthy in order to avoid the potentially negligible downside of consuming acrylamide, as might be interpreted after reading a Proposition 65 warning.[11]

In Post Foods, the California Court of Appeal found that Proposition 65 warnings on breakfast cereal were, in fact, preempted due to the exposure warning's conflict with the FDA's longstanding policy encouraging consumption of whole grains and breakfast cereal.[12] The court cited obstacle preemption as the reason for its decision, stating that a well-documented record of the FDA analyzing a particular type of product and establishing federal policy in favor of using that product preempted the Proposition 65 warning labels.[13]

Shortly thereafter, the California Supreme Court denied a writ petition, but ordered the court of appeal decision to be depublished upon request by both citizen plaintiffs' groups and the Office of the California Attorney General.[14] While this case remains depublished, the Post Foods decision is a recent example of how federal guidelines and policies not officially codified as law may preempt state law.

With respect to the listing of glyphosate as a carcinogen under Proposition 65, a similar struggle arises due to FIFRA's regulatory domain over the labeling of pesticides and herbicides.

FIFRA requires the registration of all pesticides through an approval process, during which the EPA determines whether the pesticide will cause unreasonable adverse effects on the environment or human health.[15] As part of this registration process, the EPA must approve a pesticide's label, which the manufacturer then must use without modification.[16]

Separately, FIFRA imposes an express preemption of state law, declaring that a state may "not impose or continue in effect any requirements for labeling or packaging in addition to or different from those" required by the EPA.[17]

This regulatory background informs decisions like the U.S. Supreme Court's decision in Bates v. Dow Agrosciences LLC, which interprets the preemptive scope of FIFRA.[18] Dow Agrosciences found that state law is preempted when: (1) a state law mandates requirements for labeling or packaging, and (2) when the state law imposes a labeling or packaging requirement that is in addition to or different from those required under FIFRA.

Hardeman v. Monsanto

Hardeman v. Monsanto is in the vanguard of the latest preemption spat between FIFRA and Proposition 65. Aside from Hardeman, approximately 5,000 cases have been filed in federal court similarly alleging a failure to warn of the risk that the herbicide Roundup, manufactured by the defendant, may cause cancer.

The first case on appeal before the Ninth Circuit, Hardeman v. Monsanto was originally brought in the U.S. District Court for the Northern District of California, where a unanimous jury found Monsanto — later acquired by Bayer AG — liable for failing to warn that Roundup could cause cancer. The jury in the district court awarded plaintiff Ed Hardeman more than $80 million in economic and punitive damages, which the judge later reduced to $25 million.

Monsanto filed its appeal, arguing that the verdict in the lower court contradicted regulatory findings and sound science. Monsanto's chief argument focuses on the EPA's repeated findings that glyphosate, the chemical that the plaintiff alleges caused his medical condition, is not a carcinogen and not a risk to public health when used in accordance with its current label.

It further contended that complying with the lower court's verdict is both expressly preempted by Section 136v(b) of FIFRA, and impliedly preempted because any warning label placed on its herbicides in accordance with Proposition 65 would be in conflict with guidance from a federal agency.

The guidance referenced by Monsanto in its brief is the EPA's Aug. 7, 2019, letter to Monsanto stating that it would no longer approve product labels claiming that glyphosate is known to cause cancer.[19]

Similar to the guidance issued by the FDA following litigation related to federally regulated products, the EPA stated that placing a cancer warning on a product containing glyphosate pursuant to Proposition 65 was a false and misleading statement, which does not take into account the EPA's assessments published in 1991, 2005, 2015 and 2017 finding that the chemical was not likely to be carcinogenic to humans.[20]

The EPA stated in a subsequent press release that a cancer warning for glyphosate would be a false claim that does not meet the labeling requirements of FIFRA.[21] In the same press release, the EPA further objected to California's listing of glyphosate as a carcinogen under Proposition 65 as "irresponsible," due to the EPA's multiple findings that glyphosate does not pose a cancer risk.[22]

The State's Amicus Argument

In an amicus curiae brief filed in support of Hardeman, the state of California asked the Ninth Circuit to reject Monsanto's appeal to overturn the $25 million verdict. The state argued that state warning requirements pursuant to California's Proposition 65 were not preempted by FIFRA.

While Section 136v(b) of FIFRA specifically forbids a state from imposing any additional or different requirements on pesticide labeling or packaging than those implemented by FIFRA, the state argues that Proposition 65 is a state law parallel to FIFRA, because Proposition 65 warning labels are necessary to protect health and the environment. California argues that a state can continue to enforce the determination of carcinogens to protect public health and the environment.

Interestingly, the state is silent on how frequently it, in fact, enforces Proposition 65

through the civil courts. Court records reveal that the state brought no Proposition 65 enforcement actions to judgment in 2019, and only resolved one dispute in 2018.[23]

To avoid express federal preemption, it argues that the warning requirements under Proposition 65 do not impose any labeling requirement in addition to or distinct from those imposed by FIFRA. Specifically, it points out that FIFRA's express preemption provision is limited to labeling and packaging, and therefore would not apply to point-of-sale warnings that are permitted under Proposition 65.

The state relies heavily on the 1992 Chemical Specialties Manufacturers Association decision for support. However, Chemical Specialties Manufacturers Association was decided prior to the 2016 and more recent amendments to Proposition 65 — which function to shift the burden of providing warnings away from a retail seller and place them squarely on the shoulders of the manufacturer.

Title 27 of the California Code of Regulations, Section 25600.2(a), for example, requires the administering agency of Proposition 65, the Office of Environmental Health Hazard Assessment, or OEHHA, to "minimize the burden on retail sellers of consumer products to the extent practicable."

The 2016 amendment to the language of the regulations, which revised the section from generally indicating that "warning materials … shall be provided by the manufacturer, producer, or packager of the consumer product rather than by the retail seller," to a specific directive to "minimize the burden on retail sellers," shows that the legislative intent behind the warning regulations is to place the burden on the entity who includes the listed chemical in the consumer product.[24]

More often than not, and certainly in the Monsanto case, the manufacturer is the entity adding listed chemicals into its product. OEHHA itself has published interpretive documents acknowledging that manufacturers have the primary responsibility of providing warnings since "manufacturers usually will have greater knowledge than retailers of the product's chemical content and whether it causes chemical exposures that require a warning."[25]

The state's advocacy for cancer warnings for glyphosate at the posted sign level reverses its new regulations, and shifts the warning responsibility to retailers in a way that the regulations have clearly sought to avoid.[26] Therefore, the intent behind the 2016 revision of Proposition 65 may impact the interpretation of how Chemical Specialties Manufacturers Association applies to the preemption dispute related to Proposition 65, since the change in law may accordingly necessitate an update of case law.

The legislative intent behind the 2016 revision of Proposition 65 may very well make point-of-sale warnings, which are often entirely managed by the retail entity, an unsuitable alternative to on-product Proposition 65 exposure warnings for glyphosate.

Oral argument in Hardeman v. Monsanto is anticipated, but not yet scheduled.

Rebecca M. Lee is an associate, Christopher W. Smith is counsel and Mark E. Elliott is a partner at Pillsbury Winthrop Shaw Pittman LLP.

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[1] Title 27, California Code of Regulations, Section 25704.

[2] See National Family Farm Coalition v. USEPA, Ninth Circuit Case No. 17-70810 (pending challenge to the EPA's registration of Dow AgroSciences LLC's herbicide Enlist Duo containing glyphosate); National Assoc. of Wheat Growers v. OEHHA, E.D. Cal. Case No. 17-2401 (challenging Proposition 65 warnings for glyphosate as a carcinogen as a violation of the First Amendment).

[3] See D-Con Co. v. Allenby, 728 F. Supp. 605 (N.D. Cal. 1989); Chem. Specialties Mfrs. Ass'n v. Allenby, 958 F.2d 941 (9th Cir. 1992).

[4] Title 27, California Code of Regulations, Section 25602(a).

[5] Chem. Specialties Mfrs. Ass'n, 958 F.2d at 946-948.

[6] Gade v. Nat'l Solid Wastes Mgmt. Assn., 505 U.S. 88, 98 (1992).

[7] Id.

[8] Fla. Lime & Avocado Growers Inc. v. Paul, 373 U.S. 132, 142-43 (1963).

[9] Id.

[10] OEHHA, Acrylamide, https://oehha.ca.gov/chemicals/acrylamide.

[11] Statement from FDA Commissioner, https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-fdas-support-exempting-coffee-californias-cancer (Aug. 29, 2018).

[12] See Post Foods, supra, note 7.

[13] Id. at 654.

[14] See Post Foods LLC v. Superior Court, 235 Cal. Rptr. 3d 641, 655 (Ct. App. 2018), as modified on denial of reh'g (Aug. 15, 2018), review denied and ordered not to be officially published (Oct. 31, 2018).

[15] 7 U.S.C. § 136a(c)(5)(C); 7 U.S.C. § 136(bb).

[16] 7 U.S.C. § 136j(a)(1)(E).

[17] Id. § 136v(b).

[18] Bates v. Dow Agrosciences LLC, 544 U.S. 431, 443 (2005).

[19] U.S. Environmental Protection Agency, Aug. 7, 2019, https://www.epa.gov/sites/production/files/2019-08/documents/glyphosate_registrant_letter_-_8-7-19_-_signed.pdf.

[20] Id.

[21] U.S. Environmental Protection Agency News Release, Aug. 8, 2019, https://www.epa.gov/newsreleases/epa-takes-action-provide-accurate-risk-information-consumers-stop-false-labeling.

[22] Id.

[23] See California Office of the Attorney General, https://oag.ca.gov/prop65/report/judgments-by-plaintiffs?year%5Bvalue%5D%5Byear%5D=2019; see also California Office of the Attorney General, https://oag.ca.gov/sites/all/files/agweb/pdfs/prop65/2018-summary-settlements.pdf.

[24] https://oehha.ca.gov/media/downloads/crnr/side-sidearticle6.pdf.

[25] See also Final Statement of Reasons, Title 27, California Code of Regulations, Regulations for Clear and Reasonable Warnings, https://oehha.ca.gov/media/downloads/crnr/art6fsor090116.pdf, at p. 35.

[26] See 27 C.C.R. § 25600.2(a).