Federal Challenges to Proposition 65: New Paths to Litigation and Lessons for Challenging State Laws

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Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986, passed as a ballot initiative in California in 1986. Proposition 65 primarily aimed to protect drinking water, barring certain chemical releases into sources of drinking water. Over time, however, the drinking water protections were eclipsed by the obligation to provide a "clear and reasonable warning" prior to exposing a person in California to substances listed as known to the state to cause cancer or reproductive harm.

Over the decades, Proposition 65 has faced federal law challenges. Historically, courts have mostly upheld Proposition 65 against preemption challenges. In the last year, however, some notable cases have upheld federal preemption or constitutional theories to invalidate Proposition 65 warning requirements for a particular substance.

Before exploring these new paths in Proposition 65 litigation, some background is necessary. The California Office of Environmental Health Hazard Assessment (OEHHA) is charged with identifying substances that are known to the state to cause cancer or reproductive harm based on specific listing criteria under Proposition 65. The listing criteria is controversial and has been the subject of legal challenges. Even so, at present, OEHHA has listed more than 900 chemicals that are designated as either carcinogens, reproductive toxicants, or both.

OEHHA also identifies "safe harbor exposure levels," which are no significant risk levels for carcinogens or maximum allowable dose levels for reproductive toxins. If a person who causes the exposure can show that the exposure to a listed chemical does not exceed the safe harbor exposure level, that person is not obligated to warn. These levels, denominated in units of micrograms per day, are not published for every listed substance. Consequently, the regulated community sometimes must calculate for itself the warning trigger levels for each chemical and product exposure. Safe harbor exposure levels also are not exclusive, as persons can use other scientifically valid methods to develop alternative warning trigger levels for any given listed chemical in a specific product or for a class of products.

There are three categories of exposures under Proposition 65: (1) consumer product, (2) occupational, and (3) environmental. This article focuses on litigation related to consumer product exposures. A consumer product exposure occurs when a consumer handles a product containing or emitting a listed chemical in a way that results in either an oral, dermal, or inhalation exposure. OEHHA has issued "safe harbor warning" regulations for consumer product exposures. Use of OEHHA's safe harbor form is deemed to deliver a "clear and reasonable warning" under Proposition 65. Warnings may appear on a product, its packaging, or a posted point-of-sale sign in California retail locations.

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History of Federal Challenges to Proposition 65

Proposition 65 has been subject to legal challenges since adoption, including a series of claims that certain federal laws preempted Proposition 65. Over the decades, however, federal and state courts have ruled that Proposition 65 is not preempted by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Federal Hazardous Substances Act (FHSA), the federal Food, Drug, and Cosmetic Act (FDCA), and other laws. The initial standard for federal preemption of Proposition 65 arose in a 1989 case involving FIFRA. Preemption arose only if *all* possible consumer product warnings that would satisfy Proposition 65 (i.e., warnings on the product and posted signage) conflicted with federal law. *D-Con Co. v. Allenby*, 728 F. Supp. 605 (N.D. Cal. 1989). The Ninth Circuit in 1992 also adopted this standard. *Chem. Specialties Mfrs. Ass'n v. Allenby*, 958 F.2d 941 (9th Cir. 1992). Many arguments that federal law preempts Proposition 65 have failed because Proposition 65 regulations allow for consumer product warnings by signs—meaning that Proposition 65 does not always require a warning on a product's label or labeling.

The majority of courts evaluating preemption arguments refused to find preemption. That said, a few courts found obstacle preemption (a subclass of conflict preemption) in cases where a federal agency developed policies or rules for specific products. Other federal theories, such as federal constitutional challenges to Proposition 65 warnings, have been largely untested.

Post Foods and Obstacle Preemption

Many food and over-the-counter drug producers have struggled with potential requirements for Proposition 65 warnings on ubiquitous products like coffee, tea, meats, and cereals. Acrylamide is one listed substance that has received attention recently. Since the 1950s, acrylamide has been synthetically

produced for uses in polymers, cement, and wastewater treatment. Acrylamide also is generated naturally in a variety of carbohydrate-rich foods (such as breakfast cereals) when they are baked, roasted, or fried. Acrylamide was added to the Proposition 65 list by OEHHA in 1990 as a carcinogen and later as a reproductive toxin.

Last year, a group of manufacturers of breakfast cereals successfully argued that the federal scheme for promoting consumption of whole grains preempted Proposition 65 because Proposition 65 warnings might mislead or discourage consumers from consuming whole grains in breakfast cereals. *Post Foods, LLC v. Sowinski*, 25 Cal. App. 5th 278 (2018), *as modified on denial of reh'g* (Aug. 15, 2018), *review denied and ordered not to be officially published* (Oct. 31, 2018). The California Court of Appeal relied on the doctrine of obstacle preemption, a type of conflict preemption that allows for preemption of state law if it is an obstacle to the accomplishment and execution of the full purposes and objectives of Congress, even when there is no direct conflict between state and federal law. The court of appeal concluded that Proposition 65 warnings on cereals would frustrate the Federal Drug Administration's (FDA's) policy to promote the consumption of whole grains, as supported by two detailed letters from the FDA citing how consumers respond to cancer warnings. Notably, the FDA took the strong position (which was well documented) that foods with whole grains should not carry Proposition 65 warnings. *Post Foods*, 25 Cal. App. 5th at 235.

The court of appeal in *Post Foods* relied in part on an earlier California Supreme Court decision holding that an FDA ruling on labeling nicotine replacement therapy products preempted Proposition 65 warnings for nicotine in those products. *Dowhal v. SmithKline Beecham Consumer Healthcare*, 32 Cal. 4th 910 (2004). The supreme court in *Dowhal* reasoned that federal policy favored reducing smoking. Proposition 65 warnings on nicotine replacement therapy products likely would lead consumers to believe that those products were as dangerous as smoking. Notably, the supreme court found that this obstacle to federal policy arose for all forms of Proposition 65 warnings—including on-product and posted sign warnings.

The court of appeal also relied in part on an earlier trial court decision that held that Proposition 65 warnings for methylmercury in tuna were preempted by FDA's policy of promoting the consumption of fish. *People ex rel. Lockyer v. Tri-Union Seafoods, LLC*, No. CGC-01-402975, 2006 WL 1544384, at *55 (Cal. Super. Ct. May 11, 2006), *aff'd on other grounds sub nom. People ex rel. Brown v. Tri-Union Seafoods, LLC*, 171 Cal. App. 4th 1549 (2009). In that case, the court noted that FDA had engaged in a detailed balancing of the benefits of fish consumption and the risks of methylmercury. Similar to *Dowhal*, obstacle preemption depended on a well-documented record of the agency analyzing a particular type of product and establishing federal policy in favor of using that product.

Post Foods effectively revived obstacle preemption for Proposition 65 after over a decade of lying dormant. The key to the *Post Foods* decision, as with those cases on which the court of appeals relied, was that in each case the FDA had issued some kind of specific ruling or policy that conflicted with a Proposition 65 warning for that particular category of products. Without that level of specificity, courts generally have not found preemption. *E.g., Comm. of Dental Amalgam Mfrs. & Distributors v. Stratton*, 92 F.3d 807, 813 (9th Cir. 1996) (holding that medical device amendments to the federal FDCA did not preempt Proposition 65 warnings for dental device).

On appeal of the *Post Foods* decision, the California Supreme Court denied the petition for writ of certiorari but ordered the court of appeal decision not to be published—meaning that the *Post Foods* decision cannot be cited as controlling legal authority. Both citizen plaintiffs' groups and the Office of the Attorney General requested depublication, contending that the unique nature of the facts in *Post Foods* should not establish controlling precedent. While the supreme court accepted the request for depublication, any finding of obstacle preemption for Proposition 65 likewise would be limited to the specific type of products involved. In the long term, if no obstacle preemption cases are published involving narrow or specific areas of federal policy, some could argue the doctrine of obstacle preemption is not viable. That said, even though unpublished, the *Post Foods* decision is well-known to the Proposition 65 legal bar and thus will continue informally to influence enforcement practices and future lawsuits.

Zeise Constitutional Challenge

Before last year, multiple courts, including the Ninth Circuit, had considered federal challenges to Proposition 65 claiming that FIFRA preempted Proposition 65 warnings. All those decisions held that FIFRA did not preempt Proposition 65. Facing OEHHA's listing of glyphosate as a carcinogen in 2017, various agricultural trade groups filed a complaint in the Eastern District of California and took a different tack, claiming (among other things) that Proposition 65 warnings for glyphosate as a carcinogen violated the First Amendment. *Nat'l Ass'n of Wheat Growers v. Zeise*, 309 F. Supp. 3d 842 (E.D. Cal. 2018).

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Under First Amendment case law, compelled speech about a commercial product must represent "purely factual and uncontroversial information." The trade groups argued, and the trial court agreed, that the warnings for glyphosate did not meet that standard because only one health organization, the International Agency for Research on Cancer (IARC),

had found a carcinogenic association for glyphosate. Other health organizations found no evidence that glyphosate caused cancer. Moreover, IARC's finding was that glyphosate was "probably carcinogenic." The *National Association of Wheat Growers* court explained that a Proposition 65 warning would convey the message that glyphosate's carcinogenicity was an undisputed fact. Accordingly, on considering a motion for a preliminary injunction, the trial court found that the trade group plaintiffs had established a likelihood of succeeding on the merits and issued the preliminary injunction.

In response to the *Starbucks* decision, in 2018 OEHHA subsequently issued a proposed regulation that would exempt coffee from a Proposition 65 cancer warning for acrylamide or any other carcinogen found in coffee as a result of the roasting and brewing process.

National Association of Wheat Growers follows a strategy mirrored in other cases of attacking the underlying science of OEHHA's carcinogenicity or reproductive toxicity determinations. For example, in *Baxter Healthcare Corp. v. Denton*, the California Court of Appeal upheld a declaratory judgment in favor of a medical device manufacturer ruling that it did not have to provide Proposition 65 warnings for DEHP, a chemical plasticizer, in its medical devices like intravenous bags. 120 Cal. App. 4th 333, 347 (2004). There, the court reasoned that the manufacturer had established by a preponderance of the evidence that DEHP did not cause cancer because the listing of DEHP was based on studies of liver cancer in mice and rats caused by a mechanism not present in humans. The innovation in *National Association of Wheat Growers* is to apply a science-based claim to challenge a Proposition 65 warning requirement through a federal constitutional claim. The lesson here is to carefully examine the basis for any listing under Proposition 65 to determine if there exists a viable argument that compelled speech is false or inaccurate.

OEHHA Responds to Litigation with Regulations

The courts remain the key domain for challenges to Proposition 65 warning obligations. OEHHA, however, has shown that it can respond to court cases with some alacrity, effectively attempting to reverse courts by adopting new regulations. Of course, OEHHA likely will have multiple motivations for any given regulation. One potential consideration, however, is that OEHHA is seeking to manage legal risk inherent in appellate decisions on key legal points. Sometimes the State of California's legal interpretations of Proposition 65 prevail, sometimes not.

While the court of appeal in *Post Foods* found obstacle preemption for acrylamide in cereals, a trial on Proposition 65 warnings for acrylamide in coffee reached a markedly different conclusion. *Council for Educ. and Res. on Toxics v. Starbucks Corp.*, No. BC435759 (Cal. Super. Ct. filed Apr 13, 2010). Similar to the process with cereals, acrylamide appears in coffee as a result of the roasting process. In one phase of that trial, the trial court ruled that Proposition 65 warnings for acrylamide in coffee were not preempted by federal law. Obstacle preemption was not present there because there were no prevailing FDA policies or frameworks to promote coffee consumption.

In response to the *Starbucks* decision, in 2018 OEHHA subsequently issued a proposed regulation that would exempt coffee from a Proposition 65 cancer warning for acrylamide or any other carcinogen found in coffee as a result of the roasting and brewing process. The regulation would not apply to any substances that were added to or mixed with coffee. The regulation, if adopted, would represent an agency attempting to preempt a trial court decision.

While the *Starbucks* case involves an example of OEHHA attempting to exempt products from warnings, OEHHA apparently is motivated by the opposite goal in another proposed rulemaking. In 2015, in a case involving alleged exposures to lead in baby food and certain juices, the California Court of Appeal upheld the trial court's conclusion that defendants accurately calculated exposures to lead in the subject products. *Envtl. Law Found. v. Beech-Nut Nutrition Corp.*, 235 Cal. App. 4th 307 (2015), *as modified on denial of reh'g* (Apr. 16, 2015). The appellate court found that substantial evidence supported the methodologies of averaging lead content across several products and averaging lead exposure over time using the geometric mean. Defendants prevailed, and no Proposition 65 warnings on the subject products were needed.

In response to the *Beech-Nut* decision, at least in part, OEHHA issued proposed amendments to regulations used for calculating consumer exposure that would average samples from only the same facility and would require using the arithmetic mean to calculate the rate of intake. Comments on this proposal closed in December 2018. OEHHA has not yet acted. Adoption of those proposed amendments would signal OEHHA is attempting to reverse or undermine the *Beech-Nut* decision through regulation.

In addition to these responses to court decisions, OEHHA again signaled it may be trying to manage litigation risks by avoiding court decisions on key legal topics. OEHHA arguably acted to head off preemption challenges related to Proposition 65 warnings on pesticides.

In 2016, OEHHA issued sweeping amendments to the regulations for "safe harbor warnings." The 2016 amendments took full effect for products manufactured on or after August 30, 2018. The new warning regulations changed the wording of the safe harbor warnings and (for many scenarios) included a new pictogram with a yellow triangle containing an exclamation point. Some pesticide manufacturers noted that federal law controls whether a pesticide product label includes the word "warning." In response, OEHHA recently amended the safe harbor warning regulations to allow pesticide products instead to use the word "notice." This does not necessarily

resolve all issues for pesticide manufacturers. Federal law still controls pesticide labels, so on-product Proposition 65 warnings, if not reviewed and approved by EPA, could be considered mislabeling under federal law.

Lessons for Proposition 65 Litigants

Overall, the *Post Foods* and *National Association of Wheat Growers* cases indicate that any Proposition 65 litigant should evaluate obstacle preemption and federal constitutional issues in their case. Wholesale claims for express or field preemption have been less successful than narrower claims of obstacle preemption. In addition, these cases show that it is essential to understand the science undergirding the listing of a carcinogen or reproductive toxin.

Beyond Proposition 65, obstacle preemption is important for any environmental litigator to consider if challenging the applicability of a state environmental law. The Proposition 65 cases reviewed here provide a road map to suggest the contexts that could lead to successful obstacle preemption arguments. In addition, with any requirement to label or warn, the First Amendment provides a clear basis to challenge a requirement lacking a sound scientific foundation.

Finally, we note that agencies like OEHHA seem increasingly willing to use regulatory action in response to judicial decisions. In deploying "regulatory preemption," agencies like OEHHA could be aiming to limit judicial review by constricting the nature and scope of issues to be litigated or simply are mitigating the risks of unexpected outcomes inherent in all litigation.