Proposition 65: A National Problem

WARNING: The State of California Contains A Law Known To Cause Heartburn, Ulcers, and Extreme Ostrich-Like Behavior Among Otherwise Sensible Business Persons Nationwide.

By: Peter McGaw

Ladies and Gentlemen: From the Land of Fruits and Nuts, all packaged and ready for export, we bring you...

PROPOSITION 65!!!!!!

So what's the big deal? After all, California's Proposition 65 is almost fifteen years old now. If you or your clients haven't bumped into it – or been run over by it – by now, it probably doesn't affect you, right? Wrong.

While the length of Proposition 65's list of endangered chemicals grows linearly, the number of private "enforcement" efforts it has spawned expands geometrically. It is no longer unusual to see private enforcement actions commenced in blocks of twenty, fifty or even one hundred at a time, each with thousands or tens of thousands of potential violations carrying penalties of up to $2500 per violation.

Nothing succeeds like success, and the "private attorney generals" in California have certainly been successful in lining their own pockets while imposing tremendous economic burden on manufacturers, distributors and retailers in California. Three hundred fifty million dollars in "recovered" attorneys fees and hundreds of millions more in penalties (of which the Proposition 65 private enforcer gets to keep 25%, leading to their frequent designation as "Bounty Hunters") is just the start.

Add to that hundreds of millions of dollars that Proposition 65 enforcement has cost business in defense costs, "disgorged" profits, "voluntary" contributions to "charitable" causes, lost business, and reformulation and re-labeling expenses and the financial impact of ignorance is staggering. Small size is no guarantee of safety: in fact, many of the private enforcers prefer to target the small operation that does not have the financial ability to mount a strong defense.

And the impact of Proposition 65 is not limited to the left coast. Virtually any manufacturer, distributor or retailer of products anywhere in the country exposes itself to Proposition 65 enforcement if it wants to take advantage of the booming California economy as a market for its wares. Whether you or your clients manufacture or distribute brass key blanks, baby powder, cosmetics, building materials, art supplies, small engines, medical devices, or almost any other product which either incorporates or uses any one of the over 660 "listed" chemicals, you are at risk.

Sticking your head in the sand won't make it go away, so if you have never heard of Proposition 65, or just haven't thought about it for a while, it's time to sit up and pay attention!

So, What's This "Prop 65" Thing?

In November 1986, California voters (not the legislature – we don't do things the easy way out here) enacted "The Safe Drinking Water and Toxic Enforcement Act of 1986," still known by its designation on the ballot, "Proposition 65" (or more familiarly, just "Prop. 65") . Marketed to the voters as the way to stop harmful exposures to toxic chemicals, Proposition 65 passed overwhelmingly. The idea, at least on paper, was to allow people to eliminate carcinogens and reproductive toxicants from their lives.

Proposition 65 accomplishes its advertised goal in two ways. First, it prohibits any company with 10 or more employees from, in the course of doing business, "knowingly" causing or contributing to an exposure of an individual to chemicals on the "Proposition 65 list" without first providing that individual with a warning. No warning requirement applies whether the exposure is to a consumer, an employee in the workplace, or simply to individuals living in their normal, daily environment.

Second, Proposition 65 prohibits any company with 10 or more employees from, in the course of doing business, "knowingly" causing or
contributing to the discharge of any chemical on the Proposition 65 list into a “source” of drinking water in the state. Since California has declared virtually every drop of surface water and ground water to be potentially a “source” of drinking water, the scope the Proposition 65 “discharge prohibition” is extremely broad.

Although Proposition 65 requires the exposure or discharge to be done “knowingly,” this does not provide much comfort or protection to the unwary, out-of-state manufacturer or distributor or the out-of-state based retailer. “Knowingly” under the statute simply means the party knew that some miniscule exposure or discharge was possible. It does not mean the party knew the exposure or discharge was harmful or unlawful, nor does it exonerate the purposefully ignorant. “Knowingly” excludes only those exposures or discharges that arise without accident or negligence. If you choose to do business in California, you better inform yourself of the requirements or bear the consequences.

Nor are you “off the hook” simply because your product does not actually incorporate a Proposition 65 chemical in its manufacture. If simply using your product might expose the user to a Proposition 65 chemical, or discharge a Proposition 65 chemical to a source of drinking water, you fall within the statute. Thus, lawnmower engines and jet-skis (which release benzene and other gasoline constituents) and diesel forklifts (which release diesel particulates) have been targeted by the Proposition 65 Bounty Hunters. Even the staid old business suit has not escaped Proposition 65 attention: dry-cleaning solution residues on freshly cleaned suits allegedly contributed to the discharge of perchloroethylene.

Chemicals “Known to the State” to Cause Harm

Proposition 65 does not cover every chemical (yet!) Chemicals are put on the Proposition 65 list only after they are “known to the State of California” to be carcinogens or “reproductive toxicants.” A reproductive toxicant is something that either causes birth defects or disrupts the reproductive system in adults. The Proposition 65 list currently contains over 660 chemicals and chemical compounds. Several dozen more are under consideration for listing.

A substance can be placed on the Proposition 65 list through a variety of mechanisms. First, the State’s Office of Environmental Health Hazard Assessment (“OEHHA”, which must be pronounced “oh-WEE-ha” if you want to be mistaken for someone versed in Prop. 65 lore) maintains two committees of technical experts, the Carcinogen Identification Committee, and the Developmental and Reproductive Toxicant Identification Committee (the “CIC” and the “DART” Committee in alphabet-soup terminology). These two committees review the scientific evidence and literature to determine whether nominated chemicals have the potential to cause cancer, reproductive toxicity, or both. A chemical can also make the Proposition 65 list by being designated as a carcinogen or a reproductive toxicant by virtually any other administrative agency or other “authoritative body.” Whether one of these other sources has engaged in sound scientific practices before designating a substance as a carcinogen or reproductive toxicant is often the subject of much debate.

Once a chemical makes the Proposition 65 list, manufacturers and others in the chain of distribution have 12 months to implement warnings and 20 months to cease all “contributions” to discharges to sources of drinking water. After that, they are fair game for either the government or the “private enforcers.”

That’s a Warning?

Under Proposition 65, the form of the particular warning is up to the potentially liable party. The statute simply requires the warning to appear in a way that will render it “likely to be read and understood by an ordinary individual under customary conditions of purchase or use.” While the language of the statute appears to give wide discretion to the person providing the warning, in practice, anyone deviating from the “approved” format is likely to be challenged by the Bounty Hunter community. Thus, it is routine to use the “safe harbor” language deemed by regulation to be adequate.

In the case of carcinogens, this language reads: 

“WARNING: This Product Contains A Chemical Known To The State Of California To Cause Cancer.”

For consumer products, the warning can either be placed directly on the product’s label, or it can be prominently displayed near the product at the retail outlet.
For occupational exposures, the warning can also be placed on the product’s label. Additionally, it can be included on the MSDS, or a sign can be posted at the workplace stating the “area” contains a chemical known to the State to cause cancer/ reproductive harm (as applicable).

“Environmental exposures” are the most difficult for which to meet the warning requirement. Environmental warnings can be accomplished by posting a sign in the affected area, mailing notices to people living in the affected area, or by public media announcements targeting the affected area.

Under any of the scenarios in which warnings must be given, there is substantial concern about the efficacy of the warning. The safe harbor language does not require any information about the particular chemical, its toxicity, or the dose an individual might expect to receive, nor does it provide any information about the relative significance of the expected exposure or effective methods of reducing exposure below some level of significance. Even OEHHA’s own description of the meaning of a Proposition 65 warning admits the “exposure” may be nonexistent. It states:

When a warning is given by a business, it means one of two things:

(1) the business has evaluated the exposure and has concluded that it exceeds the no significant risk level; or

(2) the business has chosen to provide a warning simply based on its knowledge about the presence of a listed chemical, without attempting to evaluate the exposure. In these cases, exposure could be below the Proposition 65 level of concern, or could even be zero. (emphasis added).

The proliferation of “generic” Proposition 65 warning labels on products and in areas around the state is seen by many as both over-warning (where there is no significant risk) and under-warning (where the user cannot distinguish between a significant risk and an insignificant risk), yet the Bounty Hunters are adamant that adding “qualifications” to the standard language is not permitted. (Does the fact that this would make their “enforcement” efforts much more factually intensive and therefore more difficult enter into their decisions? You be the judge.)

Of course, supporters point out that private enforcement efforts have led to the removal of thousands of pounds of “toxic” chemicals from the California environment, and throughout the country, through reformulation of products as a result of Proposition 65 settlements. Proponents also claim that consumers are more knowledgeable of their surroundings and the products they buy because of the warnings placed on them, although no one has yet found the driver who chose not to enter a parking garage because of the sign at the entrance stating, “This Area Contains Chemicals Known to the State Of California to Cause Cancer and/or Birth Defects or Other Reproductive Harm.”

Don’t Drink that Water!

Unlike the “exposure without first warning” prohibition, the “discharge to source of drinking water” prohibition under Proposition 65 does not allow you to avoid liability by giving an advance warning. Any discharge is prohibited if it will more likely than not pass into a source of drinking water. This prohibition applies even though the discharge might otherwise be authorized.

Until recently, the Bounty Hunters largely ignored the discharge prohibition, but even this is changing as the Bounty Hunter field grows more crowded. Suits arising out of leaking underground storage tanks and two-stroke watercraft engines have now brought the discharge prohibition to the fore.

Digging Out from a Prop. 65 Claim

Although Proposition 65 suggests that manufacturers should bear the primary burden for providing warnings, it does not exempt distributors and retailers from the warning requirement. Thus, if the manufacturer fails to provide adequate warnings, everyone in the chain of distribution can potentially be liable for the hefty Proposition 65 penalties. Frequently, distributors and retailers are joined in Proposition 65 suits simply because they did not react quickly enough to get the product off their shelves when notified of a Proposition 65 violation. A quick reaction to such notice is imperative, both to reduce the number of potential violations and to provide evidence of mitigating conduct for the jury, should the claim ever get that far.

Of course, the Proposition 65 defendant is not completely adrift. The available defenses, however, are limited and most can be and very expensive to establish. First, Proposition 65 does not apply to businesses with fewer than ten employees. Be careful though. “Employees” includes temporary and part-time employees. If, even counting temporary and part-time employees, your business has fewer than ten employees, consider yourself lucky. You get a pass on Proposition 65 liability, for now. Just don’t grow!

For those who do not fit into the under-10-employees category, consider that Proposition 65...
does not require warnings for matters that are preempted by federal law. Just don't spend too much time considering it. In every circumstance but one, the courts have held that Federal preemption is not a defense to a Proposition 65 claim. For example, while Proposition 65 cannot compel the addition of a Proposition 65 warning to a pesticide label (which is preempted by the Federal Insecticide, Fungicide and Rodenticide Act), both Federal and State courts have held that Proposition 65 is not a "labeling" law per se, but is rather a "consumer protection" law which can be complied with by methods other than labeling such as by using point-of-sale signs and area warnings. Thus, Proposition 65 is not preempted by FIFRA. Similar rulings have been made in other areas normally subject to Federal preemption, such as medical equipment subject to the Medical Device Amendments to the Federal Food and Drug Act.

The single exception to the "no preemption" rulings is in the area of "workplace safety." Although the provisions of Proposition 65 have recently been incorporated into the California OSHA program, an express condition of the approval from Federal OSHA is that those provisions cannot be enforced against purely out-of-state manufacturers. Of course, this "exemption" from the requirement to provide warnings applies only in occupational settings. Consumer and environmental exposures still trigger the warning requirement.

Having failed to get a quick dismissal on size or preemption grounds, the Proposition 65 defendant should next consider whether the exposure in question is actually harmful. Although Proposition 65 is intended to prevent harm to individuals, the "enforcer" is not required to demonstrate that any actual harm has occurred. In fact, one of the novel features incorporated by the drafters of Proposition 65 is the requirement that the defendant bear the burden of proving that a warning is not required. To do this, the defendant must prove more than just the absence of actual harm from exposure. The defendant must show there would be "no reasonable likelihood of harm." Of course, Proposition 65 statutorily establishes a very stringent standard for such a showing.

For carcinogens, the defendant must demonstrate that daily, lifetime exposure at the expected level of exposure will cause "no significant risk" of contracting cancer. "No significant risk" is defined as one excess case of cancer in a population of 100,000 exposed daily for a 70-year lifetime. The specific elements of the required quantitative risk analysis are also set by regulation.

The exposure level for avoiding a reproductive toxicant warning is even more stringent. To avoid the warning requirement, the defendant must demonstrate that exposure will be 1,000 times below the highest level at which there is "no observable effect." Thus, for a substance which begins to produce observable effects at exposures or dosages of ten parts per million, but does not produce observable effects at one part per million, the level which triggers a Proposition 65 warning requirement is 1,000 times below the one part per million level, or one part per billion! Moreover, the "No Observable Effect Level" is not determined based on all available evidence. The No Observable Effect Level must be based on the "most sensitive" study, and must disregard studies that show no reproductive effect at all.

The cost of mounting a solid, scientific defense can be quite steep. Add in the pre-conditions on the evidence that may be considered, and the extremely low orders of magnitude of exposure which will trigger the warning requirement even in the absence of actual harm, and it is not surprising that very few cases have been tried on the basis of exposure levels.

The defendant bears the burden of disproving a violation of the discharge prohibition, too. The defendant must show (a) no detectable amount of the Proposition 65 substance entered the source of drinking water, or (b) that the amount which did enter the source of drinking water would not exceed the level at which a warning would be required if an individual were exposed through the drinking water. Though the discharge might be for a just brief episode, the Bounty Hunter will argue that the defendant must show no likely harm based on a lifetime exposure. Thus, a defense to a "discharge prohibition" claim carries the same burdens as a defense to a "warnings" claim, with the added difficulty of establishing the actual level of material in the drinking water itself.

**Enforcement or Extortion?**

A second twist inserted into Proposition 65 by its drafters is the mechanism for enforcement. As with many environmental statutes, Proposition 65 includes a "citizens suit" provision allowing enforcement actions to be brought by individuals or organizations acting in the "public interest" if the government does not take the enforcement initiative after receiving a "60-day Notice." Since the California Attorney General’s office is swamped by as many as 150 or 200 "60-day Notices" at a time, far more than the small Proposition 65 Division can
investigate and handle, private enforcement has become the trademark of Proposition 65 litigation.

Unlike most citizens’ suits provisions, which generally require that any penalties collected go to the government, Proposition 65 specifically requires that 25% of any penalty recovery go straight into the pocket of the private “enforcer.” It is this provision, more than any other, which has been responsible for the rise of the Bounty Hunters. “Public interest groups” consisting of little more than one or two individuals and a lawyer comb retail outlets up and down the state looking for products that typically contain Proposition 65 substances but do not carry the Proposition 65 warning. Frequently, these products list their ingredients, so the Bounty Hunters do not even need an independent testing laboratory.

Once an “offending” product has been located, the trap is closed. The “violation” has occurred, the 60-day Notice letter goes out, and the checkbook gets opened. Any person or company violating Proposition 65’s warning or discharge requirements is liable for penalties of up to $2500 per day per “violation.” The potential penalties can be astronomical. For example, each person exposed without a warning is considered a “violation.” The statute of limitations for penalties is one year. Multiplying a year of individual sales by $2500 per person per day quickly adds up to enormous dollar figures. Since a jury assesses penalties, and there are no regulatory or judicial “guidelines” for assessing these penalties, any Proposition 65 trial carries with it the risk of enormous “blackboard” numbers and a runaway jury. Where the violations cannot be seriously contested, settlement is almost unavoidable. The Bounty Hunter adjusts the price of settlement accordingly.

Then, having identified a “victim product,” the private enforcers come back again and again, searching out the same product from different manufacturers or targeting the identical product for different violations (after all, why reinvent the wheel?) Many years after the well-publicized litigation against major manufacturers of nail polish containing toluene, 60-day notices are still going out to smaller manufacturers of nail polish and other cosmetic products who have yet to add the Proposition 65 warning to their containers. In other instances, suits against manufacturers for occupational or environmental exposures are being brought, even after earlier claims for consumer exposures were settled. There are even cases where a second “citizens group” has pursued a claim for the same product and the same type of exposure even after a settlement was reached with another Bounty Hunter organization. The ability of one such group to enter into a res judicata settlement barring other claims is still uncertain.

Adding Insult to Injury

Proposition 65 does not include any provision allowing for injunctive relief. Not to worry. California has Business and Professions Code section 17200, the “unfair competition” statute. Under this statute, anyone doing business in violation of any other law is guilty of “unfair competition.” Although the unfair competition statute does not allow the recovery of damages, it does provide for injunctive and other equitable relief, including the “disgorgement” of “unlawfully gained profits.” Thus, it is routine to see an “unfair competition” claim joined with a Proposition 65 claim, allowing the enforcer the full panoply of monetary and injunctive remedies.

Similarly, Proposition 65 does not contain an express attorneys fees provision. Again, no problem for the private enforcer. California has a “Private Attorney General” attorneys fees statute which allows anyone acting primarily “in the public interest” to recover their attorneys fees. “Private Attorney General” fees claims are routine in Proposition 65 matters, and often the “attorneys fees” component of a settlement exceeds the “penalty” component.

National Implications

As observed earlier, the impact of Proposition 65 is not simply limited to California companies selling California products in California. Proposition 65 applies to any person or entity engaged in any form of business in California. The ramifications, however, can extend well outside the State’s boundaries.

For example, many manufacturers produce products with Proposition 65 labels for sale in California, but ship products without those labels to the other 49 states. This practice requires extreme care to ensure the proper products go to the proper place. For example, if a carton or two of non-Proposition 65-labeled products mistakenly gets shipped into California, the ever-present private enforcers will find them. Because Proposition 65 does not exonerate the manufacturer or the distributor if the threatened exposure occurs through negligence or accident, a manufacturer or distributor may be liable for Proposition 65 violations if it could have reasonably anticipated that its non-labeled product could end up in California, even though by accident.

There are also examples where the California Proposition 65 label was introduced into evidence in personal injury suits outside of California. As one can imagine, a jury that believes an injured plaintiff was not told that a product is “known to the State of California” to cause harm will have the impression that a manufacturer is “hiding” adverse information. Substantial punitive damages have
been assessed outside California where the California label was given to the jury.

**Staying Out of Trouble**

As with many “environmental laws” the best defense is simply to be proactive. In other words, do a compliance audit sooner rather than later. Check the MSDSs you receive from your suppliers. They may themselves have Proposition 65 warnings. If so, pass them on.

Compare the Proposition 65 list to what you know you use. If you incorporate any of the chemicals listed into your products, consider giving the warning or be prepared to justify your decision later. Have your products tested, if appropriate, so you have a “paper trail” establishing your lack of knowledge and you due care, and watch out for the “favorites” of the Bounty Hunter community.

Lead is one of these favorites. It can be found in its raw form in fishing weights, and also in the glaze on tableware, in brass keys, and in artists’ pigments. It shows up in over-the-counter gastrointestinal remedies, and it is even used in bathroom fixtures from which it can leach into a glass of tap water. Have you ever held a galvanized nail or two in your mouth while repairing that fence in your back yard? Lead contamination in the zinc will likely result in Proposition 65 warnings on galvanized nails in the future. Zinc oxide, found in sun block and diaper rash ointment, also contains minute quantities of lead. One of the most unusual claims (in a field filled with them) alleged that firing a handgun exposes the owner to dangerous levels of lead from the back end of the weapon! (Apparently the acute lead toxicity to those standing in front of the weapon was less of a concern!)

Suppose your products don’t actually contain Proposition 65 materials, but using them could potentially contribute to exposures to those substances. It is not enough to simply think about your own products, you must also think about how they are used. The sanding grids and shapers used on drywall compound can release crystalline silica. Soldering irons and soldering guns result in nickel and lead vapors being released from solder and DHEP from melting insulation. If there is even a chance that using your products could contribute to an exposure to a Proposition 65 chemical, consider adding a warning.

With almost seven hundred chemicals and tens of thousands of uses at issue, staying on top of it all is a daunting task. No wonder some manufacturers have simply pulled out of California altogether. But California is the fifth largest economy in the world. Any company with even aspirations of a national presence cannot afford to ignore California. Neither, however, can they afford to ignore Proposition 65. The Bounty Hunters may not find you today or tomorrow, but do business in our fine state long enough, and they will, and when they do, they will hurt your bottom line. In the Proposition 65 arena, an ounce of prevention is clearly worth the pound of cure.

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