ESSENTIAL CALIFORNIA LEGAL CONTENT | WEEK OF MAY 29, 2012 An ALM Publication

THE RECORDER

The Flaws of Prop 65 Litigation

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Alternately vilified as greenmail and defended as essential consumer protection, Proposition 65 litigation can resemble the intricacy of Kabuki theatre. The findings required to initiate and successfully prosecute an action under the law have been twisted into an elaborate ritual dance. Lost in the process is the central issue of Proposition 65 litigation — whether, by handling a product in normal use, consumers are exposed to a listed chemical in excess of the threshold triggering the warning requirements (in other words, what is the dose from use of the product?). The application of more rigorous scientific method to this question would weed out meaningless cases alleging theoretically demonstrable but statistically unlikely exposures. Left would be actions based on real exposures, whose success would facilitate the true consumer protection envisioned by Prop 65 when enacted.

Prop 65 has a lofty goal, incentivizing manufacturers, distributors, wholesalers and retailers to reformulate their product so that consumers are not needlessly exposed to listed chemicals. Beginning with the Certificate of Merit required to initiate an action, the question is exposure (what is the dose of a listed chemical from use of the product?). The legislative history of the law, especially the reforms of 2001, makes plain that plaintiffs are required to consult knowledgeable experts who inform them that it is reasonable to believe that a consumer will be exposed to a listed chemical in an amount that exceeds the warning threshold. See, for example, the SB 471 report of the Assembly Committee on Environmental Safety and Toxic Materials for its July 10, 2001 hearing.

A review of many Certificates of Merit leads to the conclusion that the plaintiff has done no such thing. The language used, which is rarely held up to the light of litigation, is often carefully crafted to let plaintiff's counsel put forth a Certificate of Merit based on such meaningless tripe as a review of the file, chats with someone alleged to have "experience" with these issues, and other obvious evasions of the intent of the 2001 reforms. Yet, strict compliance with legislative intent is mandated by statute, regulations, and case law. This is no small defect because, if the Certificate of Merit is insufficient, the complaint must be dismissed with prejudice. *Consumer Defense Group v. Rental Housing Industry Members*, 137 Cal. App. 4th 1185 (2006).

The plaintiff has an easy opening play under the structure of Prop 65 because the burden of proof is on the defendant once a *prima facie* case is made by the plaintiff. But even a *prima facie* case must demonstrate a) the presence of the listed chemical, and b) an exposure pathway. *Consumer Cause, Inc. v. Smilecare*, 91 Cal. App. 4th 454 (2001). It is this latter element that is often sorely missing not only from mention in Certificates of Merit, but also in plaintiffs' cases.

As a general rule, how do plaintiffs demonstrate exposure? They have generally undertaken a lab test that takes a piece (or pieces) of the consumer product, dissolves them in an acid strong enough to extract a listed chemical from vitrified glass (which EPA wants used for the long-term storage of nuclear wastes), and then measures the presence of the listed chemical. Plaintiffs claim that there is an association between the quantity of a listed chemical in a product and exposure. This is not factually correct. Material science makes plain that the matrix of substances composing the product or its relevant parts within which the listed chemical is present determines whether the listed chemical can be "liberated" by consumer activities or not. Yet, this fundamental fact of science is never addressed in hardly any Prop 65 cases. This twisted logic even shows up in settlement agreements, where SOP is to have "standards" set at some seemingly arbitrary concentration number. In the real world these numbers have little, if any, relationship to an actual exposure because, as noted before, the key element in determining whether an exposure will occur is the make-up and structure of the product (at the molecular level) and the quality of its creation and manufacture.

In response, plaintiffs will trot out their "NIOSH wipe test," and allege that it mimics the handling of the product by a consumer, a claim allegedly supported

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by work done by the Federal Trade Commission. Not true. Not surprisingly, such proof is never produced at deposition. Research has shown, in fact, that the FTC studies have often found no correlation between wipe tests and what is removed by actual consumer handling. In one assessment, the FTC study showed that a wipe removed between 5-times and 13-times more lead from the product than the actual handling of the product by people, depending on whether the wipe was wet or dry. There is little or no truth to the allegation that wipe tests are the same as handling by people.

Let us assume that a *prima facie* case can be made and that challenges to the qualifications of plaintiff's experts (another consideration that can often prove productive) have fallen short. How does one show exposure? Working with a variety of experts, we have developed a six-step test methodology that in fact measures exposure.

Step 1. Identify the presence of the alleged listed chemical. Because the distribution of a listed chemical is often not uniform, we put a strong acid on a cloth and rub it in discrete small sections of the product. We then analyze the results in order to learn how the listed chemical is distributed over the product. Sometimes it is uniformly present; sometimes, it is not.

Step 2. With knowledge of how the product is handled or used and where the listed chemical is present on the product, we then develop a protocol for the handling of the product in a manner that mimics real world conditions.

Step 3. Using a variety of samples of the product (to reduce the likelihood that any one sample is an "outlier"), we have real people first clean their hands and thereafter handle the product to simulate a potential exposure. We then remove the chemicals from their hands and determine the exposure to the listed substance.

Step 4. After several days have passed so that the tester's hands have recovered and are more au naturel, we repeat the exposure study and have samples of the product handled by different individuals. We use the same group of individuals (though each will handle different products than the one done in the first round of testing). We again analyze the result by removing the listed substance from their hands as a result of this second round of testing.

Step 5. At this point we have a data set. In some cases, the results show that the amount on the tester's hands was less than the amount triggering the warning requirement. For example, when we recently tested a "plastic" product that contained lead in the plastic, all the samples showed that the amount of lead on the hands of the testers was less than the 0.5 mcg. level. With this result we could definitely state that there was no warning requirement triggered because even if 100 percent of the lead on the hands made it inside the body, the exposure level was less than that triggering the warning requirement.

Step 6. In some cases the amount present on the hands will be more than the warning threshold. At that point we engage in some sophisticated modeling, based on standard data sets, of how the listed substance might be transferred from the hands to (for example) the mouth where it would be ingested. Since all such transfer actions are less than perfect, there are losses all along the way. This transfer assessment may also result in the conclusion that the exposure is less than the warning threshold trigger.

This type of testing requires careful attention to detail and execution. One must scope out potential confounding factors and address them with scientific measures to assure that the results are not skewed; attention to detail and QA/QC must be exquisite. Complex statistical assessment of test design and results may also be necessary. But that is what it takes to actually measure whether an exposure (dose from use) will occur. All the surrogates commonly used are very much flawed.

This process also eliminates the use of extreme examples of hypothetical exposure scenarios as a basis for litigation. Although such scenarios are popular with plaintiffs' experts, they are not part of the law. The OEHHA regulations make plain that normal use by average consumers is the paradigm to be applied. I have had plaintiffs' experts opine during deposition, without any relationship to the reality of how a product is used, that it would be lovingly held and used for many, many hours on end (at least some of which would, of course, be by sweaty hands), and even placed on the floor for a baby to lick like some precocious puppy. Again, normal use by the average consumer is the standard.

Assuming that my assessment is correct, you might ask — how does one put forth a meaningful standard against which to assess whether a reformulation is actually effective? Because the law requires an assessment of exposure, and because the mere presence of a listed chemical without more has no bearing on whether an exposure in excess of the warning threshold will occur, a complete rethink needs to occur. Addiction to the illusion of meaningful change has prevented asking the hard questions about material science, loading, and transfer factors.

Of course those wed to the status quo will trot out a parade of horribles, though in reality a very small fraction of what is allegedly addressed in the Prop 65 litigation process. There needs to be more adherence to the dictates of what the law says not what it has become. There is absolutely no question that some of the Prop 65 listed chemicals have little redeeming social value. Green chemistry may ultimately render Prop 65 moot, at least in terms of meaningful toxicological assessment. But the hit-or-miss approach of Prop 65, with its focus on litigation, leaves much to be desired in terms of effective social policy. Those involved in the Prop 65 dance need to make sure the law is truly administered as required, not in the flawed manner into which it has been transmogrified.

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