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**An Exaggerated And Ill-Conceived
Sense Of Risk: The Ephemeral Nature
Of California's Proposition 65**

by
Thomas H. Clarke, Jr.
Ropers, Majeski, Kohn, & Bentley



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ABOUT THE AUTHOR

Thomas H. Clarke, Jr. is a senior partner with Ropers, Majeski, Kohn, & Bentley in the firm's San Francisco office. As part of his business and commercial litigation practice, he represents both plaintiffs and defendants in Proposition 65 cases. Mr. Clarke received his J.D. in 1970 from the University of California, Boalt Hall School of Law, and his M.S. in Environmental Science from George Washington University in 1979.

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INTRODUCTION

In California you see them everywhere: In hotel lobbies and parking garages; in gas stations and automobile repair facilities; in hardware stores and liquor stores. Hollywood celebrities? Local politicians? If only. They are Proposition 65 warnings, and like tribbles¹ they seem to be multiplying exponentially.

Proposition 65 was enacted in the hope that it would provide consumers with information regarding risk, thereby allowing for informed choices about exposure. In reality, its warnings are prone to a degree of vagueness that renders the warnings meaningless. Worse, Proposition 65 calculates risk in a manner that exaggerates that very risk in a manner not found in any other environmental law, in effect divorcing the warning from any connection to

¹These were the friendly, affectionate, hungry, and constantly multiplying small furry animals from the original television series of Star Trek ["The Trouble With Tribbles"; Season 2, Episode 15 (Dec. 29, 1967)].

reality.

I. PROPOSITION 65: THE CHEMICAL LIST

Proposition 65² was overwhelmingly enacted in 1986. It has two key objectives: (a) to warn consumers about potential exposures to dangerous chemicals found in everyday “products” and settings³ and (b) to prevent the discharge of dangerous chemicals that may impact groundwater.⁴ Only the consumer product provision is reviewed in this CONTEMPORARY LEGAL NOTE.⁵

Proposition 65 turns on a list of chemicals. The chemicals on the list fall within two categories: (a) carcinogens, and (b) “reproductive toxicants.”⁶ The complete list can be found at 22 California Code of Regulations (“C.C.R.”),

²Proposition 65 is codified at Section 25249.5 *et seq.* of the California Health and Safety Code (“H.& S.C.”) and can be accessed in full at <http://www.oehha.ca.gov/prop65/law/P65law72003.html>. The regulations of the Office of Environmental Health Hazard Assessment, the agency that administers Proposition 65, can be accessed at <http://www.oehha.ca.gov/prop65/law/P65Regs.html#warning>. The California Attorney General’s regulations pertaining to Proposition 65 can be accessed at <http://caag.state.ca.us/prop65/regs.htm>.

³See Section 25249.6 H.& S.C. This article focuses mainly on consumer products, and not on the application of Proposition 65 to “settings”.

⁴See Sections 25249.5 & 25240.9(a) H.&S.C. However, only the consumer product provision of the law is reviewed in this article.

⁵Proposition 65 is applicable to any product sold in California. Every entity in the chain of creation and conveyance, from manufacturer, to wholesaler, to retailer, has potential liability. However, Proposition 65 exempts from its coverage any business with fewer than ten employees. Section 25249.11 H.&S.C. Another recognized exemption is a federally dictated warning that preempts state authority. Section 25249.6 H.&S.C. This latter exemption has recently been used increasingly by defendants in cases involving pharmaceutical, agricultural, and food products. Another exemption is for “naturally occurring substances.” 22 C.C.R. § 12501. In the tuna cases described later, this exemption is important because the defendant tuna companies allege that much of the mercury in tuna is from naturally occurring sources.

⁶This group is comprised of substances that interfere with male or female fertility or fetal development.

Section 12000.⁷ The list includes chemicals with a known adverse impact on humans. Chemicals believed to have an adverse impact on humans based on toxicological studies using accepted scientific methods (for example, so-called long-term “feeding” studies involving mice or rats) are also included on the list.⁸

The list of chemicals is developed by the Office of Environmental Health Hazard Assessment (“OEHHA”).⁹ When Proposition 65 was first passed, the Governor (who subsequently delegated his authority to OEHHA) was directed to include on the Prop. 65 list the following:

1. Those chemicals already identified by “Cal/OSHA” under Section 6382(b)(1) of the California Labor Code.¹⁰ Thus, those chemicals identified by the International Agency for Research on Cancer (“IARC”) were included. IARC listings continue to be used by OEHHA to support listing decisions even though arguably the IARC list was only to be used when the law was first put into effect.¹¹

⁷The list of chemicals can be accessed at http://www.oehha.ca.gov/prop65/prop65_list/Newlist.html. The exposure that is addressed by Proposition 65 must be to a listed chemical. Selling a substance (e.g., DHEA) that is ingested, for example, and causes an increase in a listed substance (e.g., testosterone) within the body does not qualify as an exposure. *Consumer Cause, Inc. v. Weider Nutrition International, Inc.* (2001), 92 Cal.App.4th 363, 368-370.

⁸In the toxicological trade this is known as the “prevention principle.” Basically its rationale boils down to “better safe than sorry.”

⁹Section 25249.8 H.&S.C. mandates that the Governor develop the list. The Governor however is permitted to designate a lead agency to implement this portion of the law. Section 25249.12(a) H.&S.C. Currently the lead agency is OEHHA, an agency that is part of the California Environmental Protection Agency.

¹⁰The Labor Code directed the Department of Industrial Relations to list chemicals already contained on specified public or government lists.

¹¹OEHHA’s rationale for the continued use of this listing mechanism can be found in its discussion of its notice of its intent to list two potential carcinogens (areca nut and betel quid without tobacco). See http://www.oehha.ca.gov/prop65/docs_admin/betel%20quid_areca%20nutresponses.pdf.

2. Those chemicals already identified by Section 6382(d) Labor Code. Thus, those chemicals identified by the Hazard Communication Standard of the Federal Occupational Safety and Health Administration (“OSHA”) are included. OSHA in turn includes carcinogens identified by the National Toxicology Program (“NTP”) as well as by OSHA itself.¹² OSHA listings also continue to be used by OEHHA to support listing decisions even though arguably the OSHA list was only to be used when the law was first put into effect.

There are several problems with the development of the initial list using IARC and NTP data. First, IARC itself, which is not a regulatory entity, disavows that its listings mean a chemical is a carcinogen; it also notes that the failure of its annual publication to include a chemical does not mean the chemical is not a carcinogen.¹³ IARC recognizes that its reports are merely a review of the published data. Second, NTP notes that it is not a regulatory agency, and that its listings are only meant to be the first step in hazard identification; NTP specifically notes that its evaluations do not assess carcinogenic risk to humans.¹⁴

Importantly, note that at this initial stage there was a lack of reference to lists created by the U.S. Environmental Protection Agency (“EPA”). Why is there such an omission? It is uncertain, but EPA does employ a much more sophisticated analysis for making these types of determinations. It looks at the

¹²The federal list can be found at 29 C.F.R. § 1910.1200.

¹³IARC, *Overall Evaluation of Carcinogenicity – An Updating of IARC Monographs 1 to 24* (1987), at 11.

¹⁴N.T.P., *Sixth Annual Report* (1991), at 3.

quality of the animal and human data, the availability of ancillary data (e.g., genetic toxicity, information on the impact of a chemical on the workings of the body at the molecular level), and the “weight” to be given to evidence. In this context the “weight” of evidence is an evaluation of test methods and results. This is in sharp contrast to the Cal/OSHA approach that lists a chemical unless there is data showing why it should not be listed (sometimes disparagingly referred to as the “list first, analyze later” strategy).

OEHHA now utilizes three alternative bases¹⁵ for determining whether a chemical should be placed on the list:

1. The State’s own experts determine through scientifically valid testing that a chemical is a carcinogen or reproductive toxin.
2. A recognized “authoritative body” (e.g., IARC, NTP, EPA) identifies a chemical as a carcinogen or reproductive toxin.
3. An agency of the State or Federal government requires a chemical be labeled or identified as causing cancer or reproductive toxicity.

Whichever method is used, the listing process is exempt from the California Administrative Procedure Act. This means that the listing process is not subject to the usual administrative review process and standards, and further that judicial review is procedurally difficult. Ironically, to date, there have been no challenges to the constitutionality of this process based on the lack of administrative due process, not even by directly affected parties who

¹⁵The legal basis for these approaches is found in Section 25249.8(b) H.&S.C.

would otherwise be deemed to have standing (e.g., manufacturers of a chemical that is listed or the makers of products whose goods are created using one or more of the chemicals that are listed).

Thus, a chemical may end up on the list even when the underlying data would not support a toxicological conclusion that the chemical may pose harm to humans. So, chemicals on the list range from those demonstrably certain to harm humans to the “maybe, sort of, not really sure” level. One has to question whether all these chemicals should be treated the same when the level of risk is so clearly variable. Yet the same warning sign is required by Proposition 65 whether the chemical is “methyl ethyl death” or one that might, for example, be deemed considerably less of a threat because the risk is inferentially derived from a statistical analysis built upon the allegedly positive results from two of three studies in which huge quantities of the chemical were fed to two strains of specially bred mice and one strain of rats.

II. “SAFE HARBOR” WARNING SIGNS ARE VAGUE AND MEANINGLESS

It is commonly misunderstood that Proposition 65 does *NOT* penalize the presence of a listed substance in a product, but simply penalizes the lack of a warning sign on or about a product. This lack of a warning can be enforced by

both local and State law enforcement officials, and by private citizens.¹⁶

Yet, one of the ironies of Proposition 65 is the vagueness of its warnings. The so-called “safe harbor” warning (that is, the warning that guarantees that one has complied with the law) is: “WARNING: This product contains a chemical known to the State of California to cause [cancer/birth defects or other reproductive harm].” Although other types of warnings are permitted, it is an open invitation to a lawsuit to use any warning that does not literally comply with the safe harbor warning.¹⁷

What does this warning say? Does it tell the consumer what chemical is present so that the consumer may make an informed judgment about the nature of the exposure? No. Is this important? From a toxicological viewpoint it might very well be. Some chemicals are listed because they are known human carcinogens; obviously, it is probably highly desirable to avoid these chemicals. However, many chemicals are listed based on animal studies. A consumer might choose to put less credence in such studies, or to only give credence to

¹⁶It is beyond the scope of this article to review the private enforcement mechanisms of the law. However, speaking generally, a resident gives a 60-day written notice to the litigation target, and copies the notice to the Attorney General and local law enforcement. The resident must provide the Attorney General with evidence for the basis of the alleged violation. If no law enforcement agency files suit within the 60-day notice period, then the resident may pursue a private action. Much of the alleged abuse of Proposition 65 comes from these private lawsuits that are often fronted by attorneys more interested in garnering fees than increasing public health or welfare in a meaningful manner.

¹⁷One of the few exceptions is a variation on the warning that is part of a settlement agreement. However, even then it is a chancy proposition unless the plaintiff is the California Attorney General.

listings based on studies in multiple lines of animals. These are not irrational views; far from it. Toxicologists often argue endlessly about the significance of testing in particular strains of mice or rats or other animals, and the extent to which harm in these animals under the conditions of the tests are representative of the types and threat of harm that may befall humans. Yet, Proposition 65 is plain vanilla; it conveys little information in its “safe harbor” warning.

Does the safe harbor warning inform the consumer about the quantity of exposure necessary to trigger the threat of cancer or reproductive toxicity so that the consumer can make an informed judgment about the use of the product? No. Yet, these are very practical questions. Some products are not only used daily, but the pattern of normal usage increases the potential for a continuous, ongoing exposure (e.g., cosmetics¹⁸, taking nutritional supplements¹⁹). In contrast, some products are used or touched very infrequently (e.g., stereo cords, Christmas tree lights, and many other types of wiring²⁰), and thus the actual threat from a chemical present in the product is

¹⁸Many cosmetic products are quite a mixture of substances, some of which are listed chemicals. Recently the European Union has begun to seek to eliminate such materials from cosmetics, an initiative that has rippled throughout the cosmetic industry.

¹⁹Since supplements are swallowed on a daily basis, there is little question that their contents breach the body’s barriers (e.g., skin) and thus pose an enhanced risk not seen with products not so used.

²⁰The lawsuits filed regarding these products are usually aimed at the lead allegedly contained in the polyvinyl material that is the outer coating of the wiring.

relatively minor.²¹ Again, Proposition 65 fails to draw any useful distinction; it conveys no information about the intensity of use or how that intensity correlates with the supposed threat.

Does the safe harbor warning inform the consumer of the tradeoffs between the threat and perhaps some beneficial factors that may also be present in the product? Not at all. For example, let's assume for the sake of discussion that the tuna industry loses its current battle over the labeling of tuna because of the presence of mercury, and a warning label is placed on cans of tuna. Does the safe harbor warning tell a consumer that mercury is present? No. The warning could signify methyl ethyl death, or something less threatening; the consumer is left uninformed. Does the safe harbor warning inform the consumer that there may be significant benefits from the consumption of the Omega-3 fatty acids in tuna that offset the miniscule amount of mercury in the tuna that triggers the warning requirement? Not at all.²²

One last irony should be noted. The presence of the warning sign does not inform the consumer about the quantity of a listed chemical that is present, only that it is in fact present at least at some minor threshold level deemed

²¹The lead present in many PVC materials found in electrical cords has triggered an unending parade of Prop. 65 lawsuits. But beyond initial installation, how often are such cords touched? Should a product that is rarely used be treated the same from a risk perspective as one that is used frequently? From a toxicological perspective, such usage makes all the difference in the world. Yet, Proposition 65 does not make any such distinction whatsoever.

²²For an excellent synopsis of the miniscule risk from the mercury present compared to the benefits of consumption of Omega-3 fatty acids, see http://www.economist.com/PrinterFriendly.cfm?story_id=5407595.

meaningful under the law. As noted more fully below, this is an important shortcoming because very small levels of a chemical being present may trigger the warning requirement. But, if a safe harbor warning is posted, there is no limit (at least none imposed by Proposition 65) on the quantity of chemical that may present. There is thus no distinction between a product with a little and one with a lot of chemical so long as a safe harbor warning is present; yet, from a health perspective, there is an enormous difference in risk.

The overly wide net cast by Proposition 65 in its current form has an even sadder consequence. In practice, the provisions of Proposition 65 described above mean that Californians see these warning everywhere. You cannot fill your gas tank without seeing a warning sign on the gas pump (benzene fumes); they are posted in every parking garage one enters (auto exhaust); they are present on nearly every package of electrical wires sold in a hardware store (lead in the PVC coatings on the wires); they are carried on all alcoholic beverages (teratogenicity); even crystal chandeliers, crystal ornaments, and crystal glass in desks and cabinets carry them (lead in the, what else, leaded crystal). In such an environment, the warnings have lost meaning. They rarely, if at all, represent the reality of what kills, injures, or harms in our modern world.²³

²³See, for example, the leading causes of death in 2002 as noted by the National Center for Health Statistics: <http://www.cdc.gov/nchs/fastats/lcod.htm>. A discussion by CDC of the impact (including death) of infectious diseases on the U.S. population can be found at: <http://www.healthypeople.gov/Document/HTML/Volume1/14Immunization.htm>.

Thus, although a label could provide the type of information just described and lay out meaningful explanations of threat, benefit, and the true potential for harm (even to sensitive segments of the human population), the threat of a penalty of \$2,500 per day for each product that is not labeled with the bland safe harbor warning is a very significant deterrent to making the warning meaningful.²⁴ To try and put the chemical, the usage, or the benefits of other substances present in context is to invite litigation, and the attendant costs related thereto.

Where does that leave us? It is fair to conclude that the safe harbor warning of Proposition 65 lacks context. It makes no sense from a medical or toxicological perspective. While the goals of Proposition 65 in the abstract seem desirable, its practical effect in a number of circumstances (though obviously not in all circumstances) may be not only suboptimal, but also downright harmful or counter-productive.

That being said, it should be noted that in the author's opinion, some of the so-called corrective measures proposed to "cure" the problems described herein (for example HR 4167, which has passed the House of Representatives)

²⁴Thus, the theoretical maximum penalty that can be imposed under the applicable one-year statute of limitations is \$912,500. Section 340(a) California Code of Civil Procedure; *Shamsian v. Atlantic Richfield Co.* (2003), 107 Cal.App.4th 967, 978. However, if the plaintiff is an actual purchaser of the product, then a four-year statute of limitations comes into play (Section 17208 B.&P.C.) if the violation is plead as an unfair business practice pursuant to Section 17200 of the California Business and Professions Code; under such circumstances the maximum penalty increases to \$3.65 million if it can be shown that the product was sold during the precedent four-year period without the presence of a warning.

are equally ill-informed and lacking in toxicological or medical logic. If we truly trust consumers to make intelligent choices, then public policy should be directed to provide them with meaningful information to permit informed choices. Neither bland warnings of impending doom (e.g., Proposition 65) nor federally mandated ignorance (e.g., HR 4167) serves the public good. Before the reasonableness of different solutions to this problem can be assessed, a second problem with Proposition 65 must be understood — namely, the systematic way that it exaggerates risk.

III. PROPOSITION 65’S RISK ASSESSMENT METHODOLOGY IS SKEWED

The mere fact that a product contains a listed chemical does not mean that the product is required to contain the vague and essentially meaningless safe harbor warning described above. Theoretically, there has to be an exposure to a listed chemical in an amount greater than the “no significant risk” level set for carcinogens or greater than the “no observable effect level” set for reproductive toxicants. Unfortunately, this risk assessment methodology is skewed to an absurd degree.

First, and most importantly, the plaintiff does not have the burden of proving an exposure at or above the requisite level. In the “through the looking glass” logic of Proposition 65 that the burden falls upon the defendant.

Consumer Cause v. Smilecare et al (2001), 91 Cal.App.4th 454, 469.²⁵ In other words, companies that are the target of a Proposition 65 lawsuit are “guilty until proven innocent” from an exposure perspective. Realistically, the failure to allocate this burden of proof to the plaintiff significantly increases the likelihood of frivolous litigation.

Second, the law exaggerates the level of risk at which a warning requirement must be placed on a product. For carcinogens, OEHHA regulations establish the “no significant risk” level as one excess case of cancer in an exposed population of 100,000. 22 C.C.R. § 12703. In contrast, many environmental protection agencies (e.g., EPA) frequently use a figure of one excess cancer in a population of 1 million when assessing risk. Thus a warning under Proposition 65 may be based on an impact that is 1/10 the impact often deemed worthy by the EPA. For reproductive toxicants, Proposition 65 requires that there be “no observable effect” at 1,000 times the exposure level in question. Section 25249.10 H.&S.C. Environmental protection agencies will often start with the “no observable effect” level and then build in a safety margin of 10 or 100, but rarely a margin of 1,000.

An OEHHA assessment uses as a baseline a lifetime of exposure (70

²⁵Although cases are frequently initiated by a plaintiff, case law has allowed a potential defendant, in the appropriate circumstances, to file an action seeking declaratory relief that it is not subject to the warning requirement. In *Baxter Healthcare Corp. v. Denton* (2004), 120 Cal.App.4th 333, a company demonstrated that the alleged evidence supporting the listing of a chemical was without merit.

years) at a rate of 24/7²⁶. In contrast, many environmental protection agencies have elaborate tables based on scientific studies that provide time frames, albeit conservative ones, for exposure. So, rather than 24/7, an environmental assessment outside of Proposition 65 might assume an exposure of 8 hours a day, 5 days a week, or 7 days a week; something that is more tied to reality, although, as noted, a conservative reality.

Cumulatively, Proposition 65 greatly exaggerates risk in three ways: a) by lowering the base population (carcinogens); b) by raising the “no observable effect” threshold by 1,000 (reproductive toxicants); and, c) by greatly enhancing the exposure time period to around the clock for seventy years. This latter point is of great significance because, as noted previously, many of the exposures in question (e.g., electrical cords) involve products for which the real-world exposure is often miniscule. If risk were assessed based on real-world usage, then the thresholds requiring that a warning be posted would often not be crossed.

If a defendant wishes to establish a “no significant risk” or “no observable effect” level in its defense, OEHHA regulations provide for a multitude of methodologies in assessing risk when addressing listed carcinogens²⁷ and listed

²⁶Twenty-four hours a day, seven days a week.

²⁷22 C.C.R. §§12701 et seq.

reproductive toxicants.²⁸ However, the battle of the experts that arises in such cases is expensive, and only the deepest pockets can afford such litigation costs. Beyond the issue of costs, there is something suspect about reducing the quantifiable scientific issue of whether a compound is present at dangerous levels to a courtroom war of words between “experts.”

Thus, Proposition 65’s risk assessment methodology places the burden of proof on the defendant and substantially exaggerates and removes from reality the assessment of risk. The result is that warnings are required for products whose usage in the real world does not pose even a fraction of the risk the theoretical number-crunching yields.

IV. CONCLUSION AND RECOMMENDATIONS

The goal of Proposition 65 is laudable — to help consumers make informed decisions. However, it is highly flawed. Its “safe harbor” warning is essentially meaningless in terms of conveying accurate, meaningful information that allows a consumer to make an informed decision about whether to risk an exposure. The risk assessment methodology greatly exaggerates risk, meaning that warning labels are required in many circumstances in which the risk of exposure to the listed chemical is in reality minor.

²⁸22 C.C.R. §§ 12801 et seq.

In a perfect world, Proposition 65 would be tossed in the proverbial wastebasket and redrafted. Given the politics of California that is highly unlikely to happen.

However, there are two changes that might right many wrongs: (1) changing the burden of proof, and (2) bringing reality to the risk assessment methodology. If plaintiffs have to incur the cost of proving exposures above the “no significant risk” and “no observable effect” levels, then many of the abuses commonly seen today are likely to stop. No longer could plaintiffs count on defendants rolling over because the cost of litigation is so high. They, the plaintiffs, would have to incur real costs to prove their case. Eliminating the 70-years of exposure baseline (at a rate of 24/7) for risk assessment, and instead substituting real exposure parameters, would also eliminate much of the abuse. In other words, if a product is used daily on a regular basis, then the risk assessment should reflect such usage; if the actual product usage means minor exposure, do not make absurd risk assessment assumptions.

One final thought about addressing the risk of dangerous chemicals in our society today. Many pro-Prop. 65 advocates claim that the current litigation model makes the world a safer place by eliminating harmful chemicals from commerce. Unfortunately that is not really true. Most of the litigation over the past half-decade has focused on lead. Lead is nasty stuff, no doubt about it. But, there has been very little litigation involving other chemicals on the list.

Why? Because OEHHA has determined that the safe exposure level for lead is so low, pursuant to its so-called Safe Harbor authority, that litigating over lead in products is easy, especially if a plaintiff does not have to bring real-world exposure models into play.

If we as a society truly consider some of the listed chemicals to be dangerous to humans, we should stop playing games with labels. The chemical should be phased out, and deadlines set for substitutes. If we take such an approach, we will have to address the cold, hard fact that many of life's conveniences and necessities depend on toxicologically ugly stuff (for example, gasoline contains lots of benzene, a known human carcinogen, a substance to which we are exposed every time we fill our gas tank). We can also deal with the absurdities of some of the chemicals on the list, which includes (believe it or not) some medications (e.g., the anti-seizure medication, diazepam²⁹). It is time to try to put an end to, or at least decrease the volume of, the politics of fear and look hard at what we want as a society. If we do not want some or all of these chemicals in our lives, then they should be phased out (though good luck finding substitutes for some of them). Spreading about ad infinitum bland warnings founded on weak science that inspire numbness and not considered action is not the answer.

²⁹That is, of course, why we have doctors, to help us balance the benefits and risks and determine an appropriate course of action. For example, diazepam prevents seizures, but is a teratogen; a doctor is certainly better able to help a patient assess the tradeoff and to take steps to prevent pregnancy than some vague safe harbor warning label.