PROPOSITION 65

The Safe Drinking Water and Toxic Enforcement Act of 1986

An outline prepared by the Office of the California Attorney General[1]

Last updated, July 2015

[1] This outline originally was prepared by former Supervising Deputy Attorney General Edward G. Weil and more recently has been updated by others in the Attorney General's office. It is provided for informational purposes only and should not be interpreted or cited as representing an official position of the Attorney General on any aspect of Proposition 65, its implementing regulations, or cases that construe the statute.

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I. ENACTMENT OF STATUTE

A. Adopted by vote of the people in November, 1986. Placed on the ballot by initiative process, not by the Legislature.

B. Limited Ability to Amend. Statute provides that Legislature may amend it only "to further its purposes" and by a two-thirds vote. (Initiative Statute, § 7.)

II. WARNING REQUIREMENT

"No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual." (Health & Saf. Code, § 25249.6.)

A. Plaintiff's Prima Facie Case

1. Exposure

a. Applies to all types of exposures: environmental (e.g., factory emissions), workplace, and consumer products.

b. Who caused the exposure?

c. Distinguish exposure (i.e., human contact with the chemical), from content or presence: human exposure must be shown, which cannot always be inferred from the presence of the chemical in a product or workplace. Exposure exists at first point of "contact" with the body or any inhalation, ingestion or absorption. (27 CCR § 25102(i)[2]; *Consumer Cause v. Weider Nutrition* (2001) 92 Cal.App.4th 363.)

d. Detection of the chemical: 22 CCR § 12901, now repealed, had arguably required plaintiff to prove exposure through certain types of tests. (*Mateel Environmental Justice Foundation v. Edmund A. Gray & Co.* (2003) 115 Cal.App.4th 8.) New regulation, 27 CCR section 25900, provides that no knowing and intentional exposure occurs where a defendant shows that it tested the medium according to proper procedures within the last year and the chemical was not detected. The new regulation does not apply to cases pending at the time of enactment. (*As You Sow v. Conbraco, Industries* (2005) 135Cal.App.4th 431.)

[2] In 2008, the regulations governing Proposition 65 were recodified without substantive change, moving them from title 22 of the California Code of Regulations to title 27, and renumbering them. With some exceptions, regulations formerly found at title 22, section 12xxx are now found in title 27, renumbered 25xxx. Citations in this outline are to the current numbering. Citations in reported cases and many other available documents are to the old numbering.

2. To a listed chemical: list is published. (27 CCR § 27001.)

    a. The "list" is established by the Governor's designated lead agency, the Office of Environmental Health Hazard Assessment ("OEHHA"). (27 CCR § 25102(o).) Chemicals are added to the list in four ways:

        (i) "Labor Code" Listing Mechanism: Chemicals identified by reference in Labor Code section 6382(b)(1) and 6382(d), including substances identified by the International Agency for Research on Cancer ("IARC"), EPA, OSHA, the Director of Pesticide Regulation, and other organizations, even if only proven to cause cancer in animals. (Health & Saf. Code § 25249.8(a); *AFL-CIO v. Deukmejian* (1989) 212 Cal.App.3d 425.) This provision applies on an ongoing basis, meaning that OEHHA must add new chemicals to the Proposition List as they are identified under the Labor Code sections. (*California Chamber of Commerce v. Brown* (2011) 196 Cal.App.4th 233.)

            (a) Reproductive toxins identified by the American Conference of Governmental Industrial Hygienists are included under Labor Code section 6382(d). (*California Chamber of Commerce*, 196 Cal.App.4th at at p. 265).

            (b) Chemicals cannot be added based exclusively on being listed in Group 2B by the IARC (an agency identified by the Hazard Communication Standard, a source under Labor Code section 6382(d)), which includes chemicals that are only suspected of causing cancer or reproductive harm. (*Styrene Information and Research Center v. Office of Environmental Health Hazard Assessment* (2012) 210 Cal.App.4th 1082.)

        (ii) "Qualified Expert" Listing Mechanism: Chemicals determined by the State's Qualified Experts to be "clearly shown" to cause cancer or reproductive toxicity. Two committees appointed by the Governor, the Carcinogen Identification Committee ("CIC") and the Developmental and Reproductive Toxicant Identification Committee ("DART-IC"), carry out this task. (Health & Saf. Code § 25249.8(b); 27 CCR §§12301-12305.)

            (a) OEHHA did not act arbitrarily and capriciously in listing DINH based on the CIC's recommendation; committee members considered and rejected petitioner's claims that health impacts in rats were not relevant to humans during the administrative process. (*American Chemistry Council v. OEHHA* (Super. Ct. Sacramento County, 2015, No. 34-2014-80001868) app. pending, filed May 5, 2015.)

        (iii) "Authoritative Body" Listing Mechanism: Chemicals that have been identified as causing cancer or reproductive toxicity by "authoritative

bodies" such as U.S. EPA, where sufficient evidence in the "authoritative" agency's record shows that the chemical meets Proposition 65 criteria. (Health & Saf. Code § 252498(a); 27 CCR § 25306; *Western Crop Protection Assn. v. Davis* (2000) 80 Cal.App.4th 741, *Exxon Mobil v. OEHHA* (2009) 169 Cal.App.4th 1264, 1269.)

(a) DART-IC and CIC determine which bodies are authoritative; OEHHA determines whether an authoritative body has formally identified a chemical as causing cancer or reproductive toxicity based on "sufficient evidence." (27 CCR § 25306)

(b) DART-IC declining to list a chemical under its "qualified experts" authority does not preclude OEHHA from listing the same chemical under its "authoritative bodies" authority, based on the same expert report. (*American Chemistry Council v. OEHHA* (Super. Ct. Sacramento County, 2014, No. 34-2013-00140720) app. pending, filed April 21, 2015 (affirming listing of BPA based on National Toxicology Program ("NTP") report).)

(c) The NTP's conclusion that 4-MEI caused cancer in mice was enough to justify listing under the authoritative body mechanism. Mice data was presumed to be relevant to humans absent evidence to the contrary, and the "multiple experiments" requirement necessary to show "sufficient evidence" under Section 25306(e)(2) was met through a finding of increased cancer risk in both sexes of a single species. (*California League of Food Processors v. OEHHA* (Super. Ct. Sacramento County, 2011, No. 34-2011-80000784.)

(iv) <u>"Formally Required" Listing Mechanism: Chemicals that</u> are "formally required" by another government entity to carry a cancer or reproductive toxicity warning. (Health & Saf. Code § 25249.8(a); 27 CCR § 25902.)

b. An argument that in fact exposure to the chemical at a level that would require a warning is unlikely, or even impossible, is not relevant to whether the chemical is placed on the list in the first instance. (*Exxon Mobil v. OEHHA, supra,* 169 Cal.App.4th at 1290-1292.)

c. First point of exposure must be to the listed chemical. Fact that the body biologically converts a non-listed chemical into a listed chemical does not constitute an exposure to a listed chemical. (*Consumer Cause v. Weider Nutrition* (2001) 92 Cal.App.4th 363.)

d. Carefully review meaning of listings. Some listings are very specific, while others are broad categories of compounds. For example, the listed chemical "ethyl alcohol in alcoholic beverages" does not include alcohol in herbal extracts. (*Consumer Cause v. Arkopharma, Inc*. (2003) 106 Cal.App.4th 824.)

e. A Proposition 65 claim does not fail as a matter of law when the chemical detected is not the exact chemical alleged in the original complaint, so long as there is not a "material variance between the pleading and the proof." (*Consumer Advocacy Grp., Inc. v. Poolmaster Inc.* (2013) 2013 WL 6079449 [nonpub. opn.] [finding that plaintiff's complaint alleging a product contained the listed chemical ortho-Tolidine did not fail as a matter of law when testing showed the product to actually contain a different listed chemical, ortho-Tolidine dihydrochloride, and remanding to determine if defendants were misled as to the issues of fact in the case.])

3. Knowingly: defined by regulation: (27 CCR §25102(d).)

   a. Knowledge of exposure only.

   b. Knowledge of illegality not required.

4. Intentionally

   a. Not defined in regulations; sometimes disputed in litigation.

   b. Attorney General uses tort-type definition, that the exposure need only be the result of a deliberate act, e.g., sale of a product. (See California Civil Jury Instruction 1320, "intent.") No intent to cause harm or violate the law is required.

5. Person in the course of doing business (Health & Saf. Code §25249.11(b))

   a. Does not include businesses with fewer than ten employees.

   b. Does not include government agencies. (See *Daly v. Housing Authority of the City of Los Angeles*, (Cal. Ct. App., Sept. 24, 2009, B211313) 2009 WL 3033846, *5 [nonpub. opn.] [private enforcement action dismissed because the Housing Authority is not a "person in the course of doing business" within the meaning of Proposition 65].)

6. Without clear and reasonable warning

   a. Statutory definition limited (Health & Saf. Code §25249.11(f))

   b. Content. Regulatory definition at 27 CCR § 25601:

      (i) Concise statement clearly communicating that the chemical is known to state to cause cancer, birth defects, or other reproductive harm.

(ii) Specific safe harbor language for many situations is in regulations, but variations are permitted.

c. Methods. Also defined in regulations

(i) "Safe Harbor" methods:

(a) Consumer products: labels or in-store displays are sufficient (27 CCR §§ 25603, 25603.1), but must be conspicuous (27 CCR § 25603.1(c).)

(1) Labels may raise preemption issues. (Discussion, infra.)

(2) Manufacturers who send signs to retailers for posting should take steps to see that signs are actually posted. Difficulty getting signs posted does not render regulation a "de facto labeling requirement." (*People ex rel. Lungren v. Cotter & Co*. (1997) 53 Cal.App.4th 1373, 1393.)

(3) Label on package falls within safe harbor, even if product (e.g., dental fillings) comes in a package that is not likely to be seen by consumer. (*Environmental Law Foundation v. Wykle Research* (2005) 134 Cal.App.4th 60.)

(4) Regulation providing that for prescription drugs, use of approved FDA labeling and "prescriber's accepted practice of obtaining a patient's informed consent" was held to be an acceptable "compliance method" and not an "exemption" in *In Re Vaccine Cases* (2005) 134 Cal.App.4th 438.

(b) Occupational: labels, signs, or methods that comply with federal Hazard Communication Standard. (27 CCR §§ 25604-25604.2.)

(c) Environmental (27 CCR §§ 25605-25606.2): Safe harbor methods are the "most appropriate" of either signs "in the affected area"; mailed or delivered notice every three months (22 CCR §25605.1(a)(3); or "Public media announcements which target the affected area," once every three months. (27 CCR §25605.1(a)(4).) Must be "provided in a conspicuous manner and under such conditions as to make it likely to be read, seen or heard and understood by an ordinary individual in the course of normal daily activity, and reasonably associated with the location and source of the exposure." (27 CCR §25605.2(b).)

(ii) Non safe harbor method:

(a) "[M]ethod employed to transmit the warning must be reasonably calculated, considering the alternative methods available under the

circumstances, to make the warning message available to the individual prior to exposure." (27 CCR § 25601.)

(b) This requires that the warning be "conveyed effectively" based on business's "operational experience." (*Ingredient Communication Council v. Lungren* (1992) 2 Cal.App.4th 1480, 1493-94 (holding system of ads and signs informing consumers of toll-free telephone number to call to obtain warnings not legally adequate).)

(c) Attorney General's settlement guidelines provide some additional examples of non-safe harbor warnings that will or will not draw objections to settlements. (See discussion, infra.)

B. Defenses

1. "Grace Period"

a. Exemption for exposures that occur less than 12 months after chemical is placed on the list. (Health & Saf. Code § 25249.10(b).)

b. Language of the statutory exemption refers to when "exposure" occurs, not when product is shipped.

2. No Significant Risk/No Observable Effect. The warning requirement does not apply to:

"An exposure for which the person responsible can show that the exposure poses no significant risk assuming lifetime exposure at the level in question for substances known to the state to cause cancer, and that the exposure will have no observable effect assuming exposure at one thousand (1,000) times the level in question for substances known to the state to cause reproductive toxicity, based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of such chemical pursuant to subdivision (a) of Section 25249.8. In any action brought to enforce Section 25249.6, the burden of showing that the exposure meets the criteria of this subdivision shall be on the defendant." (Health & Saf. Code § 25249.10(c).)

a. Extent of Burden: Defendant must show the level of exposure, and that the level of exposure is below the level requiring a warning. (*Consumer Cause v. SmileCare* (2001) 91 Cal.App.4th 454.)

b. Standard of proof is the preponderance of the evidence, not "clear and convincing" evidence. (*Baxter Healthcare Corporation v. Denton* (2004) 120 Cal.App.4th 333.)

c. Defendant must show either "no significant risk" or "no observable effect" standard from statute and regulations through competent scientific evidence.

General assertions that exposure is "safe" are insufficient. (*Consumer Cause v. SmileCare, supra*, 91 Cal.App.4th 454.)

d. Level of Risk deemed "significant"

(i) Carcinogens: Set by regulation at 1 in 100,000 assuming lifetime exposure at the level in question, with some variations allowed. (27 CCR § 25703(b).)

(ii) For reproductive toxins, standard is set by statute at 1 one-thousandth of No Observable Effect Level. (Health & Saf. Code § 25249.10(c).)

e. Potency of individual chemicals: Regulations set specific daily exposure levels that are deemed to fall under level requiring a warning (27 CCR §§ 25705-25709; 25805-25809.)

f. Regulations are "safe harbor" only; if business does not fall within standard, it still may attempt to prove that exposure meets overall risk standard. (27 CCR §§ 25701(a), 25801(a).)

g. Methodology: Regulations provide risk assessment methodology where no daily exposure level is set. (27 CCR §§ 25703, 25803.)

h. Level of Exposure: Regulations describe method to determine amount of chemical to which persons are exposed as multiplying the "level in question" times the "reasonably anticipated rate of exposure." (27 CCR §§ 257219(c), 25821(b).)

(i) Level in Question: the chemical concentration of a listed chemical for the exposure at issue. Exposures to the listed chemical from any other source are not counted. (27 CCR §§ 25721(a), 25821(a).) In *Environmental Law Foundation v. Beech-Nut Nutrition Corporation* (2015) 235 Cal.App.4th 307, 324-26, petn. for review pending, petn. filed April 28, 2015, the court held that a defendant can average chemical concentrations across lots instead of considering the highest levels recorded in an individual product, if supported by evidence.

(ii) Rate of Exposure: based on "average user of general product category" for time period relevant to toxicological effect. (27 CCR §§ 25721, 25821.) Less guidance as to environmental exposures.

(a) Average users v. high-end users. Only actual users of the product are considered, but the requirement is not based on the most frequent users. The appropriate measure of "average" is not defined. In *DiPirro v. Bondo Corporation* (2007) 153 Cal.App.4th 150, the court found that a trial court's use of the 75th-85th percentile of users was

reasonable. In *Environmental Law Foundation v. Beech-Nut Nutrition Corporation* , 235 Cal.App.4th at p. 321, fn. 5, the court affirmed a trial court's rejection of the 85th percentile of users as "average," but noted that setting an average is a fact specific inquiry, and in some cases, even a 95th percentile "average" may be appropriate.

(b) Averaging over time v. single doses: May allow use of long-term average (i.e., one year) exposure, e.g. for carcinogens; but for chemicals that can cause short-term harm, e.g., teratogens, single-day exposure level may be relevant. In *Environmental Law Foundation v. Beech-Nut Nutrition Corporation*, 235 Cal.App.4th at p. 328, the court affirmed estimating daily lead exposure based on average consumption of no more than four times per month, even though lead is a teratogen.

(c) Average over lifetime: Statute says "assuming lifetime exposure at the level in question(.)" The meaning of this language has been debated.

3. Federal Preemption. Statute specifically provides that the warning requirement does not apply to an "exposure for which federal law governs warning in a manner that preempts state authority." (Health & Saf. Code, § 25249.10(a).) This would seem to be true regardless of whether the statute provided for it. (See extensive discussion, infra.)

4. Defendant not responsible for exposure

a. Naturally occurring substances (27 CCR §25501). Exemption for "naturally occurring" chemicals in food only, where specific regulatory criteria are met. (See *Nicolle-Wagner v. Deukmejian* (1991) 230 Cal.App.3d 652 (upholding validity of regulation).)

(i) Whether a chemical is present in food due to natural or anthropogenic sources is a factual issue upon which a trial court's decision after trial will be upheld unless it is not supported by substantial evidence. (*People ex rel. Brown v. Tri-Union Seafoods. LLC, et al.* (2009) 171 Cal.App.4th 1549.)

(ii) Because the issue involves difficult scientific issues, the evidence of which may change over time, a finding on the issue on one case may not bar relitigation of the issue later, based on new evidence. (*Tri-Union Seafoods*, 171 Cal.App.4th at p. 1549.)

b. Ambient Air (27 CCR § 25504): business not responsible for chemicals received in ambient air.

c. Water in/water out (27 CCR §§ 25401, 25503): business not responsible for chemicals received in incoming water, if certain criteria are met.

5. Statute of Limitations

a. Prop. 65: 1 year (Code of Civil Procedure §340(1)) (*Shamsian v. Atlantic Richfield Co*. (2003) 107 Cal.App.4th 967.)

b. Unfair Competition Law (see III B, infra): 4 years (Bus. & Prof. Code § 17208).

6. Jurisdiction. Sales of even a small number of products within the state are sufficient to give court "limited" jurisdiction over an out-of-state manufacturer for purposes of hearing the Proposition 65 case. (*As You Sow v. Crawford Laboratories* (1996) 50 Cal.App.4th 1859, 1870.)

III. DISCHARGE REQUIREMENT

Statute provides at Health and Safety Code § 25249.5:

"No person in the course of doing business shall knowingly discharge or release a chemical known to the state to cause cancer or reproductive toxicity into water or onto or into land where such chemical passes or probably will pass into any source of drinking water, notwithstanding any other provision or authorization of law except as provided in Section 25249.9."

A. Plaintiff's prima facie case

1. Same as warning on most elements: knowingly, listed chemical, person in course of doing business.

2. "Intentionally" is not an element; therefore a leak or continuing accident, once the business gains knowledge of it, is subject to the prohibition.

3. Discharge or release. Term includes release from places of confinement, e.g., tanks or pipes, but does not include "passive discharge," i.e., continuing sub-surface migration of chemicals that were placed in ground or water before effective date of requirement. (*Consumer Advocacy Group v. Exxon Mobil Corp*. (2002) 104 Cal.App.4th 438.)

4. Into "any source of drinking water"

   a. Surface and groundwater; present drinking water sources, or waters identified by Regional Water Boards as suitable for domestic or municipal purposes. (Health & Saf. Code, § 25249.11(f).)

   b. Tapwater: Includes all parts of the drinking water supply system, up to the point of the tap. Therefore, faucets that release lead into water passing through them fall within the provision. (*People ex rel. Lungren v. Superior Ct. (American Standard)* (1996) 14 Cal.4th 294.)

   c. Must involve "present" source of drinking water, not proposed source. (*California v. Kinder Morgan Energy Partners, LP* (2015) 2015 WL 2405415 ["Merely proposing to use the aquifer does not render it an existing source of drinking water."].)

   d. Warning is not an issue; i.e., giving a warning is not a defense.

B. Defenses

1. Grace Period: 20 months from listing (Health & Saf. Code, § 25249.9(a).)

2. No significant risk/no observable effect (Health & Saf. Code, § 25249.9(b)(1)):

a. Exposure that would meet the exemption from the warning requirement.

b. Chemical is not detectable.

c. Where do you measure? Unresolved as to whether measurement is at point of discharge or there is some allowance for a "mixing zone."

3. AND in conformity with all laws. (Health & Saf. Code § 25249.9(b)(2).) Therefore compliance with other laws and permits (e.g., NPDES), is not by itself a defense.

IV. PRIVATE ACTIONS

A. Action may be brought by "any person in the public interest" who meets specified requirements. (Health & Saf. Code, § 25249.7(d).)

B. No "Article III" standing. Since a private action is brought "in the public interest," and not on behalf of any individual harmed by the defendant's conduct, the ordinary Proposition 65 private enforcement case is not an Article III case or controversy under the U.S. Constitution and therefore cannot be brought in, or removed to, federal court. (*Environmental Research Center v. Heartland Products* (C.D. Calif. 2014) 29 F.Supp.3d 1281; *Toxic Injuries Corp. v. Safety-Kleen Corp*. (C.D. Calif. 1999) 57 F. Supp.2d 947; *National Paint and Coatings Association v. State of California* (1997) 58 Cal.App.4th 753.)

C. Specific Statutory pre-requisites for suit:

1. Sixty Day Notice: Must give sixty days notice before filing suit. (Health & Saf. Code, § 25249.7(d).

a. Notice given to alleged violator, Attorney General, District Attorney of any county in which the violation is alleged to have occurred, and City Attorney of cities with over 750,000 population where violation is alleged to have occurred.

b. Regulation, 27 CCR section 25903, establishes more specific requirements for content of notice.

c. Notices must set forth sufficient facts to meet the regulatory requirements of specificity, and failure to do so renders complaint subject to demurrer. (*Yeroushalmi v. Miramar Sheraton* (2001) 88 Cal.App.4th 738.)

d. Overbroad notices that do not distinguish facilities for which a violation is alleged from others, for which "there are no specific, individualized facts, but which depend on unverified probabilities," and which do not give the Attorney General "meaningful information on which to decide whether to bring a claim" are not valid. (*Consumer Defense Group v. Rental Housing Industry Members*

(2006) 137 Cal.App.4th 1185, 1210-1211. See also *Consumer Advocacy Group v. Kintetsu Enterprises ["Kintetsu II"]* (2007) 150 Cal.App.4th 953.)

e. A variance between the facts alleged in the notice and the facts later proven is material only if the notice "misled defendants to their prejudice in maintaining their defense on the merits." (*Consumer Advocacy Group, Inc. v. Poolmaster, Inc.* (2013) 2013 WL 6079449 [nonpub. opn.].)

f. When initial complaint does not include a Proposition 65 cause of action, notice requirement is satisfied when notice is given at least 60 days before plaintiff amends the complaint to allege a Proposition 65 violation. (*Cortina v. Goya Foods, Inc.* (2015) __ F.Supp.3d __ [2015 WL 1411336].)

g. A plaintiff cannot "plead around" the Proposition 65 notice requirement by bringing a consumer protection action. However, a claim that a company misled the public by misrepresenting its compliance with Proposition 65 can proceed without meeting the notice requirement. (*Sciortino v. Pepsico, Inc.* (N.D. Cal. 2015) __ F.Supp.3d __ [2015 WL 3544522].)

2. Certificate of Merit

a. Legislative amendment effective 1/1/2002 requires notice alleging failure to warn to be accompanied by certificate of merit declaring adequate basis for suit, and underlying supporting facts must be submitted confidentially to Attorney General. (Health & Saf. Code, §§ 25249.7(d)(1), 25249.7(i).) Note that the requirement does not apply to notices alleging only a violation of the discharge requirement, section 25249.5.

b. Failure to provide Certificate of Merit for any case filed after 1/1/2002 is fatal, and cannot be cured by new notice and amendment of existing complaint. (*DiPirro v. American Isuzu Motors* (2004) 119 Cal.App.4th 966; but see *Center for Self-Improvement and Community Development v. Lennar Corporation* (2009) 173 Cal.App.4th 1543 [Center's lack of corporate status at time of serving notice did not render notice statutorily defective, and may be cured with subsequent revival of status].)

c. A party must "have sufficient information *at the time of filing suit* to provide a reasonable basis for concluding that there is merit to each element of the action on which the plaintiff will have the burden of proof," or else the certificate of merit may be found defective. (*Physicians Committee for Responsible Medicine v. Applebee's International, Inc.* (2014) 224 Cal.App.4th 166, 180 [sustaining a demurrer without leave to amend after plaintiff's counsel admitted that plaintiff "had not conducted a factual investigation regarding warnings before filing the lawsuit."])

d. Regulations adopted by Attorney General set forth requirements for Certificates of Merit. (11 CCR § 3100-3103.)

D. Separation of Powers: Upheld against allegation that the citizen suit provision violates the constitutional separation of powers. (*National Paint & Coatings Assn., supra.*, 58 Cal.App.4th 753.)

E. Reporting Requirements: Statutory amendment in 1999 (S.B. 1269, Ch. 599), amended citizen suit provision to require that private plaintiffs report filing and resolution of cases to Attorney General. Regulations prescribing reporting forms and timing of duty to report adopted by Attorney General at 11 CCR § 3000-3008.

F. Judicial Approval of Settlements. (Health & Saf. Code, 25249.7(f)(4); Stats. 2001, c. 578 (S.B. 471, § 1.).)

1. Any settlement ("other than a voluntary dismissal in which no consideration is received from the defendant") in a private Proposition 65 enforcement action must be submitted to the court by noticed motion. The settlement may not be approved unless the court finds that:

(A) Any warning that is required by the settlement complies with Proposition 65;

(B) Any award of attorney's fees is reasonable under California law; and

(C) Any penalty is reasonable based on specific criteria set forth in the penalty provision of the statute.

2. In addition to the specific statutory factors, the court must consider other factors relevant to whether the settlement is just and in the public interest. (*Consumer Advocacy Group v. Kintetsu Enterprises of America ["Kintetsu I"]* (2006) 141 Cal.App.4th 46, 61-62, *Consumer Defense Group, supra*, 137 Cal.App.4th at 1207-1208.) This includes issues such as the scope of any release from future liability, whether one side may opt-out of the agreement. (*Consumer Advocacy Group, supra*, 141 Cal.App.4th at 63-64.) It also includes whether the underlying notices of violation are valid. (*Consumer Defense Group, supra*, 137 Cal.App.4th at 1209.)

3. If one of these factors is not satisfied, the court may only decline to approve the settlement, not modify its terms. (*Leeman v. Adams Extract & Spice, LLC* (2015) 236 Cal.App.4th 1367)

4. Settlement and all supporting materials must be provided to the Attorney General, "who may appear and participate in any proceeding without intervening in the case." (Health & Saf. Code § 25249.7(f)(5).) Regulations adopted by Attorney

General require 45 days advance notice of hearing to Attorney General. (11 CCR §§ 3000-3008.)

5. Attorney General's published Settlement Guidelines provide some indication of provisions that likely will draw objection from Attorney General. (11 CCR § 3200-3204.)

6. Attorney General may appeal approval of a settlement over his objection. (*Consumer Cause v. Johnson & Johnson* (2005) 132 Cal.App.4th 1175, 1179, n.2, *Consumer Defense Group v. Rental Housing Industry Members* (2006) 137 Cal.App.4th 1185, 1204-1206.)

7. "Collusive" Settlement not permitted. Notwithstanding the lack of an Article III standing requirement, a settlement in which the plaintiff acknowledged that the defendants' products had never violated the law and then purported to establish industry-wide standards for chemical exposure from medical devices was found not to present any "justiciable controversy" and to require that the case be dismissed, rather than that the settlement be approved. (*Consumer Cause v. Johnson & Johnson* (2005) 132 Cal.App.4th 1175, 1180.)

8. If a settlement is reached before an action is filed, there is no action in which judicial approval can be sought, but the settlement still must be reported to the Attorney General, who must make it publicly available. (Health & Saf. Code, § 25249.7(f)(1) ["any private person settling any violation of this chapter alleged in a notice…shall…submit to the Attorney General a reporting form that includes the results of that settlement[.]"])

9. The language of a Proposition 65 warning is not clear and reasonable if it is "without foundation", meaning it is not supported by evidence in the record. (*Physicians Committee for Responsible Medicine v. McDonald's Corporation*, (2010) 187 Cal.App.4th 554, 572.).

G. Preclusive Effect. A judgment pursuant to stipulation in a case by one private party has preclusive effect on a lawsuit filed by another private party raising the same claim, even where the settling case was filed after the precluded case. (*Consumer Advocacy Group v. Exxon Mobil Corp.* (2008) 168 Cal.App.4th 675.) The settled action, however, cannot preclude claims not raised in the sixty-day notice, e.g., claims for a listed chemical not identified in the notice. (*Ibid*.) Previous cases had suggested without so holding. (*Consumer Cause v. Johnson & Johnson, supra,* 132 Cal.App.4th 1175, *Consumer Defense Group v. Rental Housing Industry Members, supra*, 137 Cal.App.4th 1185, *Consumer Advocacy Group v. Kintetsu Enterprises, supra*, 141 Cal.App.4th 46.)

   a. The case does not address whether a private settlement could bar a public prosecutor, and the Attorney General's position is that it cannot.

b. In an unpublished ruling, the Second District Court of Appeal held that an out-of-court warning agreement between the Attorney General and shipping terminal owners over diesel exposures did not preclude continued litigation in a private action as to issues the Attorney General's agreement did not resolve. (*Bradfield v. APM Terminals Pacific, LTD.*, (Cal. Ct. App., Sept. 8, 2009, B206739) 2009 WL 2859066 [nonpub. opn.].)

V. OTHER IMPORTANT ISSUES

A. Relief

1. Injunction. Note: Private plaintiff obtaining a preliminary injunction probably is subject to the bond requirement. (*Mangini v. J.G. Durand International* (1994) 31 Cal.App.4th 214.)

2. Civil Penalties: "not to exceed $2500 per day for each such violation" (Health & Saf. Code § 25249.7(b).

   a. "Violation" not specifically defined, but is argued by plaintiffs and the Attorney General to mean each exposure without warning, which can generate very large potential penalties.

   b. Amendment in 2001 provides criteria for court to consider in assessing a penalty, e.g., willfulness, deterrent effect. (Health & Saf. Code, § 25249.7(b)(2).)

   c. Plaintiff keeps 25% of the penalty, giving rise to the term "bounty hunter." Remaining portion goes to state (formerly to Department of Toxic Substances Control, now to OEHHA). (Health & Saf. Code § 25249.12(b).)

3. Other relief: e.g., restitution, reformulation; not specifically authorized.

B. Unfair Competition Law (Business and Professions Code § 17200

1. Unfair Competition Law ("UCL") formerly allowed any person acting on behalf of the general public to sue entities for any unlawful act. The Proposition 65 violation provides the predicate unlawful act.

2. Proposition 64: Initiative on November, 2004 ballot limited private UCL actions to those brought on behalf of individuals suffering harm. This has effectively eliminated use of the UCL by private plaintiffs in Proposition 65 cases. Cases brought by public prosecutors ordinarily include a UCL claim.

3. Statute of Limitations: 4 years per § 17208, regardless of statute of limitation provided under statute that made the conduct unlawful. (*Cortez v. Purolator Air Filtration Products* (2000) 23 Cal.4th 163.)

4. Penalty Provision

   a. Statutory factors for considering penalty. (Bus. & Prof. Code, § 17206(b).)

   b. Only Attorney General and District Attorneys may seek penalties under this statute.

5. Restitution/disgorgement: limited, at least in private actions by *Kraus v. Trinity Management Services* (2000) 23 Cal.4th 116, and *Korea Supply v. Lockheed Martin Corp*. (2003) 29 Cal.4th 1134.

C. No right to jury trial. The action, including civil penalties, is primarily equitable in nature and therefore there is no right to a jury trial. (*DiPirro v. Bondo Corporation* (2007) 153 Cal.App.4th 150.)

D. Federal Preemption: Decisions

1. Medical Device Amendments to Food, Drug and Cosmetic Act (FDCA)

   a. Specific preemption provision precluding state requirements different from or in addition to FDA requirements. 21 U.S.C. section 360(k).

   b. In *Committee of Dental Amalgam Alloy Manufacturers and Distributors v. Stratton*, the Ninth Circuit held that Proposition 65 is not preempted both because it is a requirement of "general applicability" and because the device in question in that case (dental amalgam) was not subject to any specific requirements. (92 F.3d 801 (9th Cir. 1996) reversing 871 F.Supp. 1278 (S.D. Cal. 1994).)

2. Nutrition Labeling and Education Act (NLEA) Amendment to FDCA. Prohibits misbranding of food and drink and expressly preempts certain state laws on misbranding. Proposition 65 is not expressly preempted by the NLEA because it does not fall within the enumerated preempted categories, does not directly conflict with FDCA requirements, and falls into the exempted category relating to food safety warnings. (*Sciortino v. Pepsico, Inc.*, (N.D. Cal. 2015) __ F.Supp.3d __ [2015 WL 3544522].)

3. USDA: Poultry Products Inspection Act (PPIA) and Federal Meat Inspection Act (FMIA) both specifically preempt state "labeling" requirements. (In a non-Prop. 65 case, though, the Ninth Circuit held that a state poultry disclosure requirement was preempted by the PPIA to the extent it required disclosures on the label, but not in advertising and promotion. (*National Broiler Council v. Voss*, 44 F.3d. 740 (9th Cir. 1994).)

a. In *American Meat Institute v. Leeman*, (2009) 180 Cal.App.4th 728, the Court of Appeal held that point of sale warnings on meat or meat products provided pursuant to Proposition 65 constitute "labeling" within the meaning of FMIA's preemption clause, and are therefore preempted.

b. In *Physicians Committee for Responsible Medicine v. McDonald's Corporation*, (2010) 187 Cal.App.4th 554, a nonprofit brought action against several chain restaurant corporations for being in violation of Proposition 65 for failure to warn that its grilled chicken contained a carcinogen. The Court of Appeal held that:

(i) The Proposition 65 Safe Harbor Warning does not conflict with the FMIA and therefore is not preempted.

(ii) A proposed warning that adds a reference to "grilled chicken" within the safe-harbor warning does not conflict with federal law, but the Court expressed no view on whether such warning is clear and reasonable under Proposition 65.

(iii) Alternative proposed warnings that identify types of chicken besides "grilled chicken" are not clear and reasonable because there is no evidence in the record that any chicken besides grilled chicken contains PhIP.

4. Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Specifically preempts state "labeling" requirements. Prop. 65 was found not to require "labeling" as defined and therefore was not preempted. (*D-Con Company v. Allenby*, 728 F.Supp. 605 (N.D. Cal. 1989) (Federal Insecticide, Fungicide and Rodenticide Act); *Chemical Specialties Manufacturers Association v. Allenby*, 744 F.Supp. 934 (N.D. Cal. 1990), affirmed 958 F.2d 941 (9th Cir. 1992), *cert. denied* 113 S.Ct. 80 (Federal Hazardous Substances Act and FIFRA).

5. Federal Hazardous Substances Act. Similar to FIFRA, also addressed in Chemical Specialties Manufacturers Association. Also found not preempted in *People ex rel. Lungren v. Cotter & Company* (1997) 53 Cal.App.4th 1373.

6. Consumer Product Safety Improvement Act (CPSIA). This statute adopted in 2008 made a variety of changes to the Consumer Product Safety Act and Federal Hazardous Substances Act, adopting stringent new requirements for lead and phthalates in toys and childrens articles, among other things. It includes an express savings provision that protects Proposition 65 from preemption, stating that "Nothing in this Act [CPSIA] or the Federal Hazardous Substances Act shall be construed to preempt or otherwise affect any warning requirement relating to consumer products or substances that is established pursuant to State law that was in effect on August 31, 2003." (CPSIA § 231(b).)

7. Federal Occupational Safety and Health Act.

a. Preempts additional state requirements unless part of a State OSHA Plan. Proposition 65 requirements were added to State Plan after mandate by court in *California Labor Federation v. Occupational Safety and Health Standards Board* (1990) 221 Cal.App.3d 1547.

b. Subsequently, the Ninth Circuit has held that where a general subject matter, e.g., warnings for diesel equipment, is within the scope of the federal Hazard Communication Standard, even if it is not subject to any specific federal requirement, it preempts Proposition 65 requirements, unless they were specifically incorporated into the State Plan. (*Industrial Truck Association v. Henry* (9th Cir. 1996) 125 F.3d 1305, reversing 909 F. Supp. 1368.)

c. Incorporation of Proposition 65 into State OSHA Plan was approved by federal OSHA in 1997 (62 Fed.Reg. 31,159 (June 6, 1997), but with three conditions: (1) methods of giving warnings provided under the Hazard Communication Standard could be used to provide any additional warnings required by Proposition 65; (2) the state would take actions to assure that Proposition 65 does not render decisions in private enforcement matters less effective than other matters; and (3) Proposition 65 could not be applied to occupational exposures to products manufactured outside of California. This action was upheld against industry challenge in *Shell Oil Company v. U.S. Department of Labor* (D.D.C. 2000) 106 F.Supp.2d 15.

d. Cal/OSHA has adopted a regulation imposing reporting requirements on private persons bringing Proposition 65 actions concerning occupational exposures. (8 CCR § 338.)

8. Over-the-Counter Drugs and Cosmetics

a. 1997 FDA Modernization Act specifically preempts any additional state regulation of OTC Drugs and Cosmetics (21 U.S.C. § 379r(a)(2), but specifically exempts Proposition 65 from the preemption provision (by providing that it does not apply to any state requirement adopted by initiative before 1997). (21 U.S.C. § 379r(d)(2).)

b. In *Dowhall v. SmithKline Beecham Consumer Healthcare* (2004) 32 Cal.4th 910, the California Supreme Court considered the application of this provision in the context of nicotine-patch smoking-replacement products, which the FDA had determined by rulemaking petition should not carry the Proposition 65 warning, in favor of a much weaker warning. The Court held that:

(i) The anti-preemption provision did not preclude the application of normal "conflict preemption," under which, if the Proposition 65 requirement actually and irreconcilably conflicts with FDA requirements, it must give way.

(ii) FDA's previous refusal to require a warning on a product would not by itself be deemed a sufficient basis to create a conflict, otherwise the "anti-preemption" provision for Proposition 65 would become a nullity.

(iii) While FDA's formal action on a rulemaking petition was sufficient to create a conflict on the facts of that case, it does not appear that FDA letters and other communications are by themselves sufficient to do so.

(iv) FDA's determination that, for this product, the desire to promote the use of products that help people stop smoking overrode any need for a stronger warning, was within its authority, and created an actual conflict with the Proposition 65 warning, even though the Proposition 65 warning would have been truthful.

E. Primary Jurisdiction: California Supreme Court decision in *Farmers Insurance Exchange v. Superior Court* (1992) 2 Cal.4th 377, gives courts discretion under some circumstances to stay an action pending result of an administrative proceeding that will resolve difficult factual issues.

F. Actions by Defendants.

1. Declaratory Relief Action to Determine Compliance. In *Baxter Healthcare Corporation v. Denton* (2004) 120 Cal.App.4th 333, the court held that a company making a product using a listed carcinogen (medical devices containing DEHP) could sue the state for a declaration that its products were exempt from the warning requirement, because DEHP poses "no significant risk" of cancer to humans, even though the plaintiff did not claim that the state had acted unlawfully in any respect.

2. Declaratory Relief Action Against Private Party Subject to Anti-SLAPP statute. In *CKE Enterprises v. Moore* (2008) 159 Cal.App.4th 262, an alleged violator identified in a sixty-day notice brought an action for declaratory relief against the noticing party. The defendant filed a special motion to strike under the Anti-SLAPP statute, Code of Civil Procedure section 425.16, which was granted. The court held that the action was subject to the Anti-SLAPP procedure, because the action arose from the protected act of giving the notice, and also held that the action was properly stricken because the plaintiff in declaratory relief did not show a probability of prevailing as required by the Anti-SLAPP statute. In a previous case involving Proposition 65, the California Supreme Court held that a defendant filing an anti-SLAPP motion did not need to show that the action was brought with the "intent to chill" the defendant's exercise of First Amendment rights, but did not address the underlying issue of whether a declaratory relief action against the noticing party was subject to the statute. (*Equilon Enterprises v. Consumer Cause* (2002) 29 Cal.4th 53.)

VI. PRACTICAL CONSIDERATIONS

A. Some burdens are on defendants

1. Contrary to common perception, the plaintiff has substantial burdens: proving an exposure, that the exposure is knowing and intentional, that there is a failure to warn, and that the defendant is a "person in the course of doing business," i.e., a business with ten or more employees.

2. Defendant bears burden of showing the level of exposure, and that the level is below level of significant risk.

a. Limited effect given standard of proof in civil case, but there may be substantial scientific uncertainty.

b. Safe-harbor no significant risk levels ease burden significantly, by establishing level of exposure below which no warning is required, but proving actual level of exposure may be difficult.

B. Expert-intensive: the following general issues all may require expert testimony, from a different expert:

1. How much of the chemical is present?

2. How much are people exposed to?

3. How much is bad for you?

4. How many people are exposed?

5. Is the warning adequate?

C. Comparison to other types of cases

1. Torts: No requirement that plaintiff show causation of injury or any damage.

2. Class actions: action is brought on behalf of public generally, not on behalf of class of affected persons; thus no "certification" process. But see discussion of settlement approval requirements, *supra*.

D. Risks and benefits of litigation

1. Possible civil penalties: can be substantial, but there is no mandatory minimum.

2. Position relative to competitors: harm to your client may depend largely on whether its competitors are similarly situated.

3. Marketplace effect of warning: for some products, effect is substantial, for others minimal.

4. Reformulation won't be ordered by court in warning case, but could become necessary if warning has an effect in the marketplace.

5. Prevailing private party may be entitled to attorney's fees under Code of Civil Procedure section 1021.5.

E. Settlements

1. Precluding future litigation. Judicially-approved settlement with a private party can preclude other private parties from bringing the same claim, but a pre-litigation settlement will not.

2. Relief may include reformulation, which parties may find more beneficial than warnings, depending on effect of the warning in the marketplace.

3. Funds may go to "environmental projects." See Attorney General's guidelines concerning nexus between basis for suit and use of funds. (11 CCR §§ 3200-3204).

F. Insurance Coverage

1. Insurance company has no duty to defend a Proposition 65 claim under their Commercial General Liability Policy because the claim seeks civil penalties, not personal injury damages. (*Ulta Salon, Cosmetics & Fragrance, Inc., v. Travelers Property Casualty Company of America* (2011) 197 Cal.App.4th 424 [holding Travelers has no duty to defend Ulta against Proposition 65 action because claim does not seek personal injury damages covered under the policy.]