

Updates on Recent Appeal Courts Decisions

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Overview

- 6 cases: 1 in the 2nd District, 5 in the 1st District
- 1 regarding fees (*Davia*)
- 1 regarding preemption (*CEH*)
- 1 regarding e-commerce/CDA (*Lee*)
- 1 addressing 998 offer (*CE&RT*)
- 2 AG's office involvement (*Lee* (p), *CE&RT* (d), *CEH* (p))
- Variety of chemicals and products: marijuana smoke through pipes, lead in crystal dishware, phthalates in vinyl costume containers, acrylamide in coffee, ranitidine in generic antacids, mercury in skin lightening creams

Lee v. Amazon, Inc.

76 Cal. App. 5th 200

- Products at issue are skin lightening or whitening creams containing high levels of mercury
 - Products contained up to 21,000 ppm mercury, reproductive toxin
 - U.S. Food and Drug Administration Mercury Limits (21 C.F.R. § 700.13(d)(2) (limit for cosmetics is 1 ppm generally and 65 ppm for “cosmetic intended for use only in the area of the eye”))

Lee v. Amazon, Inc.

76 Cal. App. 5th 200

- Amazon.com (and thus other e-commerce entities) must comply with Proposition 65's consumer warning requirement, including for sales by third party vendors through its site
- Communications Decency Act does not preempt Proposition 65—warning obligation is independent of Amazon's role as an internet service provider and duty does not stem from any role as a publisher of third party content
- A single test may be sufficient to establish the presence of a chemical when it is undisputed that the chemical is an intentionally-added ingredient.
- The voters' intention was that "knowingly and intentionally" include constructive knowledge. (H&SC 25249.6)
- Notice of violation can be the source of actual knowledge
- Is Amazon a retailer (p. 34)? And if so, is constructive knowledge sufficient?
- "Expose" means potential exposures as well as realized exposures—no need to prove individual actual exposure

Environmental Health Advocates v. Sream, Inc.

83 Cal. App. 5th 721

EHA represented by Nicholas & Tomasevic and Glick Law Group

Sream represented by Environmental General Counsel

- Alameda Superior Court ruled in favor of Sream in a motion for judgment on the pleadings
- No allegation that product contained a Prop 65 chemical or emanated any Prop 65 chemical or that the water pipes can only be used with marijuana.

Environmental Health Advocates v. Sream, Inc.

83 Cal. App. 5th 721

EAH v. Sream, Inc. (Appellate Court)

- **Direct exposures** -- original lead agency intended exposure to mean any act that “directly” brings consumer into contact with a Prop 65 chemical.
- **Informed choices** - citing to *Lee v. Amazon*, Prop 65 warning intended for “informed choices”
- **Overwarning** - proliferation of unnecessary warnings confuses the public (cites to product liability law, *Johnson v. American Standard, Inc.* (2008) 43 Cal.4th 56, 70)
- **Article 6** - discounting “reasonably foreseeable” language
- **Attorney General letters** - distinguishes AG letters

Mateel Env'tl. Justice Found. v. Fiskars Living Us

2023 Cal. App. Unpub. LEXIS 1123

The Effect of a Consent Judgment on Demurrer in Subsequent Enforcement Actions

- “[T]he applicability of the doctrine of issue preclusion or exclusive concurrent jurisdiction [cannot] be resolved at the demurrer stage when the record remains undeveloped.”
- Defendant was an entity created after asset sale in bankruptcy court. This made the effect of the consent judgment ambiguous.
 - Claim Preclusion
 - Cannot show identity of parties
 - Cannot show identity of controversies

Mateel Env'tl. Justice Found. v. Fiskars Living Us

2023 Cal. App. Unpub. LEXIS 1123

- Issue Preclusion
 - Cannot show identity of relevant facts
 - Cannot disprove public interest exception
 - Issue preclusion almost never works on demurrer anyway
- Exclusive Concurrent Jurisdiction
 - Cannot show identity of controversies
 - Cannot show that it's the same controversy
 - Doctrine of exclusive concurrent jurisdiction must be raised on demurrer
- Trial Court's Policy Notions Verboten on Demurrer

CEH v. Perrigo Co., et al.

89 Cal.App.5th 1, 12, review denied (June 21, 2023)

Prop 65 Warnings for General OTC Drugs Preempted

- Generic Zantac (ranitidine). Listed chemical NDMA.
- **Prop 65 already preempted as to prescription drugs. Does preemption also apply to OTC drugs? Court said yes.**
- Duty of Sameness - generic label has to = brand label. So, generic label can't carry the warning if the brand's does not.
- Prop 65's savings clause
- Impossibility preemption
- Labeling



CEH v. Perrigo Co., et al.

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Can a Generic Manufacturer Unilaterally Place a Prop 65 Warning? No.

- Prop 65 does not apply to “[a]n exposure for which federal law governs warning in a manner that preempts state authority.” (H&S Code § 25249.10(a).)
- Generic manufacturer must prove its labeling is the same as that of the brand manufacturer. 21 U.S.C. § 355(j)(2)(A)(v). “Duty of Sameness.”
- FDCA expressly preempts state law regarding generic drugs. 21 U.S.C. § 379r. Court agreed with defendants - duty of sameness applicable to generic prescription drugs applies to generic OTC drugs.
- Court said generic manufacturers cannot give a Prop 65 warning without violating the federal duty of sameness. *PLIVA, Inc. v. Mensing* (2011) 564 U.S. 604, 612.

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Does Prop 65's Savings Clause Apply? No.

- 21 U.S.C. §379r governing generics contains a savings clause exempting Prop 65 from express preemption. So, federal law does not expressly preempt suits under Prop 65 involving OTC drugs.
- Is there a way a generic defendant can provide warnings that satisfy both Prop 65 and federal law governing warnings? If not then federal law preempts regardless of the savings clause.
- Prop 65 warning is not preempted solely because it is not identical to a federal requirement
 - The savings clause in 379r was intended to allow Prop 65 warnings even if they result in different labeling for CA. *Dowhal v. SmithKline Beecham Consumer Healthcare* (2004) 32 Cal.4th 910.

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If Generic Manufacturer Can't Satisfy Both -> Impossibility Preemption.

- Section 379r does not entirely exclude conflict preemption, leaving impossibility or obstacle preemption. *Dowhal* 32 Cal.4th at 923.
- Impossibility preemption requires that you can't independently comply with state law without violating federal law. Applies here - duty of sameness renders it impossible to comply with both P65 & FDCA.
 - *Mutual Pharmaceutical Co., Inc. v. Bartlett* (2013) 570 U.S. 472. Defendant could not comply with state-law duty to ensure product not unreasonably dangerous and federal duty not to change its product label unilaterally

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If Generic Manufacturer Can't Satisfy Both -> Impossibility Preemption.

- *Dowhal* - nicotine cessation patches. Prop 65 warning preempted based on FDA letter expressing concern the warning would dissuade pregnant women from using product to quit smoking.
 - FDA labeling policy preempted Prop 65 where Prop 65 is "in direct conflict...or frustrates the purpose of an FDA requirement." FDA had established *federal policy* barring any warnings other than FDA warnings.
 - FDA requirement can preempt Prop 65 only "on a *basis relevant to consumer health* and not because the [warning] would frustrate the FDA's policy favoring uniformity."

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Is a Prop 65 Warning “Labeling”? Yes but?

- Labeling - can the manufacturers give Prop 65 warnings without violating the duty of sameness in labeling with the brand manufacturer’s label? No.
- Is a Prop 65 warning “labeling” such that federal law over drugs would apply? Court said yes.
 - FDCA defines is as all labels and other written, printed, or graphic matters (1) upon any article or any of its containers or wrappers, or (2) accompanying such article. (21 U.S.C. § 321(m).)
 - Includes point-of-sale, public advertising.
- Court said that it does not hold all methods of publicly communicating a warning about a drug necessarily qualifies as labeling, but it would have to satisfy both the federal duty of sameness and Prop 65. It gave no examples.

Council for Educ. & Res. on Toxics v. Starbucks Corp.

84 Cal. App. 5th 879

- Case re acrylamide in coffee
- Change to coffee regulations after the plaintiffs' successful MSJ, before remedies phase of trial, thus no public benefit & no fees
- Notice did not include coffee additives so no standing to sue on same
- 998 offer of compromise was too broad, did not accept invitation to say 998s can never be acceptable in a Proposition 65 case because of required court approval
 - Offer of settlement was penalty payment, posting of warnings, releases in public and private capacities
 - Standard release language for claims known or unknown is too broad
 - Release cannot extend beyond claims involved in the litigation

Davia v. Be Wicked, Inc.

2022 Cal. App. Unpub. LEXIS 6368

- Straightforward phthalates in vinyl product case
- Parties resolved everything but fees
- Trial court found limited success on basis of much of the fees being incurred in arguing about fees
- Reversed because Davia was successful on all of her claims and objectives and so entitled to fees (reformulation and warnings), remanded to consider the reasonableness of the fees