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12 COUNTY OF LOS ANGELES

13
14 Coordination Proceeding
Special Title (Rule 1550(b))

Case No. JCCP 4246

15
16 **THE VACCINE CASES**

**PLAINTIFFS' OPPOSITION TO
DEFENDANTS' DEMURRER TO
MASTER COMPLAINT NO. 3**

17
18 _____
This document relates to:

19 WILLIAM FISK BOTHWELL, *et al.*

20 Plaintiffs,

21 vs.

22 ABBOTT LABORATORIES, *et al.*

23 Defendants.
24 _____
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1 **I. PROPOSITION 65 REQUIRES WARNINGS TO BE GIVEN WHEN A “PERSON”**
2 **CAUSES EXPOSURE TO ONE OR MORE LISTED CHEMICALS.**

3 **A. BACKGROUND ON PROPOSITION 65**

4 Proposition 65, a state ballot measure that passed by an overwhelming 2 to 1 margin, codifies a
5 long standing public policy of the State of California. Within the Preamble to Proposition 65, the
6 People declared, in no uncertain terms, that exposures to reproductive toxins and carcinogens “pose a
7 serious potential threat” to the public health. Section 1 of Initiative Measure, Proposition 65, Nov. 4,
8 1986. The People further declared their right “[t]o be informed about exposures to chemicals that cause
9 cancer, birth defects, or other reproductive harm.” Proposition 65, §1(b).

10 Through Proposition 65, the People also expressed their distrust of government and therefore,
11 allowed for private enforcement of the law, along with other guidelines seeking to protect the Citizens
12 of this State despite the political pressures which may be placed on regulators by industry.

13 Under Proposition 65, “No person in the course of doing business shall knowingly and
14 intentionally expose any individual to a chemical known to the state to cause cancer or reproductive
15 toxicity without first giving clear and reasonable warning to such individual, except as provided in
16 Section 25249.10. “¹ The law establishes a procedure by which the state develops a list of chemicals
17 “known to the State to cause cancer or reproductive toxicity.” Health & Safety Code §25249.8.

18 The California Office of Environmental Hazard Assessment (“OEHHA”) is the lead agency
19 charged with administration of Proposition 65, which among other things includes listing chemicals, de-
20 listing chemicals, and setting No Significant Risk Levels (“NSRLs”). Proposition 65 provides clear
21 mechanisms whereby any individual can request that a specific chemical be listed or de-listed, request a
22 change in the NSRL (22 CCR §12705(b)), or obtain an “interpretive guideline” regarding any matter
23 under the Act (22 CCR § 12103).

24 The Act contains certain exemptions and affirmative defenses which are listed in H&S
25 §25249.10. One exemption provides that a warning is not required where the alleged violator can show
26 that any exposure to the consumer is below the No Significant Risk Level (“NSRL”). Health & Safety
27 Code §25249.10(c). Additionally, any business entity that employs less than 10 employees is exempt
28 from the warning requirement.

29 Proposition 65 expressly provides that violators can be prosecuted through civil actions brought
30 by the State Attorney General, District Attorneys, some other public prosecutors, and so long as some
31 preliminary requirements are met, even private parties. A private party can prosecute violations if it
32

¹Cal. Health & Safety Code (H&S) §25249.6.

1 first serves a 60-day notice of its intent to sue on the Attorney General, other public prosecutors, and the
2 alleged violator. If after 60 days no public prosecutor is diligently prosecuting the case, the private
3 party may bring suit. Health & Safety Code §25249.7(d).

4 **B. REGULATION REGARDING WARNINGS UNDER PROPOSITION 65**

5 OEHHA’s charge, as the lead agency in charge of administration of Proposition 65, includes the
6 power to implement regulations to further – not limit – the goals of the Act. Among these is a
7 regulation interpreting the meaning of “clear and reasonable” warning under Proposition 65. 22 Cal.
8 Code of Regulations (“CCR”) 12601, appropriately titled “Clear and Reasonable Warnings,” sets forth
9 in some detail the form and manner of a “clear and reasonable” warning under the Act.

10 Section 12601(b) provides for warnings in “consumer product exposures.” It then goes through
11 several methods through which a defendant can discharge its warning obligations. Regarding certain
12 types of products, OEHHA has devised alternative methods of providing a clear and reasonable
13 warning. For example, under Section 12601(b)(1)(D), OEHHA provides detailed substance and manner
14 for providing a “clear and reasonable” warning regarding alcoholic beverages, spelling out the wording,
15 size, placement, and various other aspects of a warning.

16 Under Section 12601(b)(2), OEHHA has declared that to the extent possible, the burden of
17 providing warnings rests with the manufacturer, producer or packager of a product. In that same
18 subsection, OEHHA sets forth an illustrative list of types of warnings that would satisfy Proposition 65
19 – “signs, notices, menu stickers, or labels.”

20 As with alcoholic beverages, based on certain factors unique to prescription medications,
21 OEHHA devoted a subsection to addressing warnings as they pertain to such medications. OEHHA has
22 declared that where there is FDA approved labeling, this, along with informed consent, meets
23 Proposition 65’s standards for “clear and reasonable” warning.

24 **II. DEFENDANTS’ ARGUMENTS BASED ON 22 CCR 12601(b)(2) SUFFER FROM**
25 **FUNDAMENTAL MISUNDERSTANDINGS OF THE LAW.**

26 Section 12601(b)(2)(A) was meant to allow the federally-mandated labeling and warning
27 mechanism to act as an alternative to that which is required under Proposition 65. OEHHA recognized
28 that the FDA may require specific warnings regarding a given toxin, and that those warnings may not
29 meet the standards of Proposition 65, thus subjecting the manufacturer to potential Proposition 65
30 liability.²

31 **A. SECTION 12601(b)(2)(A) IS NOT AN EXEMPTION.**

32 ²OEHHA, Revised Final Statement of Reasons (“FSR”) 22 Cal Code of Regulations 12601 (1989)
at 22-23 attached as Exhibit “A” to the Declaration of Shawn Khorrami (“Khorrami Dec.”).

1 The first flaws in Defendants' argument is their treatment of Section 12601(b)(2) as an
2 exemption to their warning obligations under Proposition 65.³ There can be nothing further from the
3 truth. Plaintiffs' Complaint, however, *cannot* be dismissed regardless of which interpretation this Court
4 accepts.

5 **1. Section 12601(b)(2) Cannot Be Interpreted as an Exemption.**

6 Section 12601(b)(2) cannot be interpreted to allow a federally-approved label, that is utterly
7 devoid of any reference to carcinogenicity or reproductive toxicity, to constitute a “clear and
8 reasonable” warning. This result would not only be absurd, but it also would render that section void as
9 contrary to the specific goals of the statute.

10 Any implementing regulation that abrogates or eliminates the duty to warn would be void as
11 contrary to the intent of the statute; regulations must be interpreted, to the extent possible, to uphold
12 their validity.⁴ “Administrative regulations that alter or amend the statute or enlarge or impair its scope
13 are void and courts not only may, but *it is their obligation to strike down such regulations.*”⁵ Courts
14 have uniformly recognized this principle.⁶ This is particularly true in the case of Proposition 65 since
15 our Supreme Court has held that, as a remedial statute intended to protect the public, Proposition 65
16 must be broadly construed to effectuate its purposes.⁷ Therefore, the only interpretation of 12601(b)(2)
17 that would not be contrary to the Act’s goals mandates that the labels, though federally approved,
18 cannot be a clear and reasonable warning under the Act.

19 **2. In enacting and amending Section 12601(b)(2), OEHHA never intended for
20 it to act as an exemption, but an alternative “clear and reasonable” warning
under Proposition 65**

21 From the outset, OEHHA was well aware that it could not create any exemptions to the statute:
22
23

24 ³*See e.g.*, Defendants’ Demurrer at 3:4-6 (“By this regulation, the lead state agency responsible for
25 administering Prop. 65 has concluded that the statute imposes on manufacturers of prescription drugs *no*
duty to warn above or beyond what is imposed by the federal Food and Drug Administration (FDA).

26 ⁴Jones v. California Interscholastic Federation (1988) 197 Cal. App. 3d 751, 759.

27 ⁵Mooney v. Pickett (1972) 4 Cal. 3d 669, 681.

28 ⁶*See e.g.*, Pacific Legal Foundation v. Unemployment Ins. Appeals Bd. (1981) 29 Cal. 3d 101, 111
29 (“administrative interpretations must be rejected where contrary to statutory intent.”); *see also*, Natural
30 Resources Defense Council v. Costle 568 F. 2d 1369, 1377 (DC Cir. 1977) (the EPA cannot create
31 exemptions to the Clean Water Act); FPC v. Texaco, Inc. 417 U.S. 380, 400 (“It is not the Court’s role .
32 . . . to overturn congressional assumptions embedded into the framework of regulation established by the
Act. This is a proper task for the Legislature where the public interest may be considered from the
multifaceted points of view of the representational process.”).

⁷People v. Superior Court (American Standard) (1996) 14 Cal. 4th 294, 314.

1 The prescription process affords an opportunity for the prescribing physician to provide
2 information where the federally required labeling does not. Of course, in the case of non-
3 prescription drugs there is no prescribing physician. The agency does not believe it can deem
4 warnings to be clear and reasonable where no warning may exist. FSR to Section 12601 at 22-
5 23 (Exhibit “A”)

6 OEHHA thus clearly states that it *cannot* deem warnings to be clear and reasonable where, *as is*
7 *the case here*, no warnings may exist. In fact, OEHHA has consistently and publicly demonstrated its
8 intent that Section 12601(b)(2) only apply to situations where the FDA-required labeling contains a
9 cancer and/or reproductive or developmental toxicity warning. This is clearly evident in the February,
10 1993 letter by OEHHA’s then Deputy Director Steven A. Book:

11 It should be emphasized that a pharmaceutical company’s reliance upon federally required
12 labeling for prescription drug is adequate for purposes of Proposition 65 only to the extent that
13 such warnings clearly communicate carcinogenicity or reproductive toxicity. In the absence of
14 information about cancer or reproductive risks on federally required labels, the drug
15 manufacturer must seek other means of communicating these hazards.

16 Here, there is no evidence – nor can there be at this demurrer stage – that there were any
17 carcinogenicity or reproductive and developmental toxicity warnings on any of the FDA-approved
18 labels for the various products at issue. Even if any of the products’ labels contained any such warning,
19 that would be an evidentiary matter in a motion for summary judgment or trial.

20 This is consistent with the plain meaning of the regulation. Nowhere in the regulation is there
21 any mention of the word “exemption.” Nowhere does it state that an FDA label satisfies Proposition 65
22 even in the absence of any warning. And with good reason: Any such exemption would be admittedly
23 beyond OEHHA’s authority.

24 **3. The Alpharma Decision Supports Plaintiffs’ Interpretation of Section**
25 **12601(b)(2)**

26 Defendants’ reliance on the trial court decision in Alpharma is misplaced. First, that case was
27 decided on summary judgment. Defendants’ demurrer was denied. Second, in Alpharma, the
28 defendant’s FDA-approved label contained an entire section on *carcinogenesis*.⁸ The Attorney General
29 of California argued that this section is not enough to satisfy Proposition 65’s “clear and reasonable”
30 standard for several reasons, among them, the fact that it was placed under the “Precautions” section
31 rather than the “Warnings” section. After considering the evidence, the Court granted defendant’s
32 summary judgment motion. This is completely consistent with Plaintiffs’ interpretation and OEHHA’s
repeated statements regarding its own regulation. Where the FDA-labeling provides for a warning
regarding carcinogenicity or reproductive and/or developmental toxicity, such warning is deemed to be
“clear and reasonable” by the State of California. Where, as here, the FDA-labeling does not contain

⁸See Lindane label attached as Exhibit “B” to Khorrami Dec.

1 any reproductive and/or developmental warning, Section 12601(b)(2) does not shield the defendants.⁹
2 Further, the very same Court that decided the Alpharma case rendered a separate decision just four
3 months later, wherein Judge Garcia denied Baxter Healthcare Corporation’s Motion for Summary
4 Judgment based on Section 12601(b)(2). In that case, Baxter’s label was silent as to the carcinogenicity
5 of the chemical in question.¹⁰ Clearly, the Alpharma Court read the regulation in accordance with
6 Plaintiffs’ interpretation.

7 **4. Where OEHHA Has Intended to Create an Exemption, it Has Clearly So**
8 **Stated Both in its Statement of Reasons and in the Text of its Proposed Rule-**
9 **making**

10 The fact that OEHHA *does not* have the authority nor does it intend to create exemptions is
11 readily apparent from its later amendments to the same regulation. Specifically, in September, 2002,
12 OEHHA again turned its attention to Section 12601, this time intending to create an exemption. In fact,
13 in its Initial Statement of Reasons, OEHHA, time and again, specifically states that “[a]ccordingly,
14 OEHHA proposes to amend Section 12601 to create an *exemption* from the warning requirement . . .”¹¹
15 Thereafter, OEHHA repeatedly confirmed its intention of creating an exemption. Furthermore, the
16 proposed amendment itself specifically read that “[a] warning . . . *is not required* in the event . . .”¹² As
17 such, to the extent OEHHA intends to create an exemption, it has no trouble so stating. Neither the
18 Final Statement of Reasons nor the original text of Section 12601 contain any language showing that it
19 was meant to act as an exemption – nor could it, lest OEHHA wish to overstep its authority and adopt a
20 regulation that is void.

21 **5. Even Where OEHHA Has Intended to Create Exemptions, it Has Ultimately**
22 **Relented, Admitting That it Has No Authority to Do so.**

23 More importantly, however, is the fact that even where the original intent was to create an
24 exemption, OEHHA eventually relented citing the fact that *it had no such authority*. In September,
25 2002, when the matter was revisited during the public comment period, OEHHA specifically
26 acknowledged that it was not intending the regulation to act as an exemption and accepted public

27 ⁹Significantly, the Alpharma Court also considered preemption, and rejected the defendant’s
28 position, ruling instead that defendant’s labeling was enough to satisfy Section 12601(b)(2).

29 ¹⁰See Exhibit “B” to the Khorrami Dec.; *see also*, Khorrami Dec. at ¶4.

30 ¹¹Initial Statement of Reasons (“ISR”) 22 California Code of Regulations Section 12601 (July 27,
31 2001) at 1 (attached to the Khorrami Dec. as Exhibit “D”); *see also*, e.g., ISR at 2 (“It is for these types of
32 situations that OEHHA proposes to adopt an *exemption* from the Proposition 65 warning requirement.”
Emphasis added.)

¹²See Original Proposed Amendment to Section 12601 (July 27, 2001) attached to the Khorrami
Dec. as Exhibit “F.”

1 comment to alter the amended language in order to further clarify this fact.¹³

2 Even if this Court were to adopt Defendants' interpretation of Section 12601(b)(2), this would be
3 no more helpful to Defendants. That is, even if this Court decides that according to the text of the
4 regulations, *any* federally approved label would constitute a clear and reasonable warning, the Court
5 simultaneously would have to strike the regulation as contrary to Proposition 65's central goal of
6 informing the public of exposures to carcinogens.

7 **6. Regardless of Defendants' Interpretation, Section 12601 Will Be Unavailing**
8 **in this Case**

9 Knowing that they cannot call Section 12601 an "exemption," Defendants may attempt to
10 request that this Court interpret it as a presumption. That is, that an FDA-approved label is the FDA's
11 statement that the product does or does not need to have a warning, and to the extent it does not, it acts
12 as a conclusive presumption that there is no such requirement under Proposition 65 either. Again, this
13 reasoning would be hopelessly flawed.

14 First, the FDA and Proposition 65 consider wholly different guidelines in determining whether a
15 warning is required. For example, the FDA's "safe harbor" levels for mercury are far greater than that
16 which is actionable under Proposition 65, and frankly, higher than any other federal agency, including
17 the EPA and the ATSDR. For this reason alone, Proposition 65 may require a warning where the FDA
18 does not and Section 12601 cannot be interpreted to create any presumption.

19 Second, there is no evidence in the record, nor can any be submitted at this stage, that the FDA
20 even considered the potential health effects of thimerosal as used in vaccines. Furthermore, even if this
21 Court were to interpret the regulation as a conclusive presumption, it would still be of no value to
22 Defendants here. This is because the Court would have to strike the regulation as it would be allowing
23 a Defendant not to warn, where a warning is clearly required under the Act.

24 **B. THE ALPHARMA DECISION IS NOT RES JUDICATA HERE**

25 Defendants claim that Plaintiffs are collaterally estopped from litigating the issue of the scope
26 and effect of Section 12601(b)(2) by the order of the San Francisco Superior Court granting summary
27 judgment in the Alpharma case, which involved a prescription shampoo product. The argument lacks
28 any merit. First, and foremost, Defendants' argument rests on an impermissible factual inquiry. Second,
29 there is no privity between Plaintiffs, suing under statutory authority granting standing to sue for the

30
31 ¹³ See OEHHA, Final Statement of Reasons ("FSR") 22 California Code of Regulations Section
32 12601 (September 5, 2002) at 3 (in response to Comment 1a) (attached to the Khorrami Dec. as Exhibit
"F"; see also, FSR, Response to Comment 1e ("OEHHA acknowledges that it *does not have the authority*
to create an exemption to the warning requirement; and therefore, modified the regulatory language to
eliminate the reference to an 'exemption' in the proposed regulation." Emphasis added).

1 benefit of the public, and the Attorney General. Third, there is an obvious and unavoidable distinction
2 between the events giving rise to this action involving thimerosal, and the events of the prior Attorney
3 General action involving prescription shampoo. Collateral estoppel cannot be applied in such
4 circumstances.

5 **1. Defendants' Res Judicata Argument Rests on an Impermissible Factual**
6 **Inquiry as to the Scope of the Consent Judgment**

7 In deciding whether the Alpharma Court's ruling bars the present action, the scope of the case,
8 the ruling, the facts and evidence considered by the Court will be crucial in determining whether
9 Plaintiffs are in privity with the AG in Alpharma and whether any issues in the prior suit were actually
10 identical. In Nakash v. Superior Court (1987) 196 Cal.App.3d 59, the Court considered the question of
11 res judicata in the context of a prior settlement. In denying summary judgment, the Court held:

12 [T]he issue of the scope of the settlement agreement is factual and must be resolved before that
13 to which res judicata assertedly applies can be determined. On this basis alone, a grant of
14 summary judgment . . . would have been improper.¹⁴

15 Defendants' demurrer offers no analysis of the scope of the Alpharma Court's ruling or the
16 evidence which that Court considered. Therefore, as a preliminary matter, whether that judgment has
17 preclusive effect, is not an appropriate subject matter at the demurrer stage as it requires the
18 consideration of evidence which is not and cannot be before this Court.

19 Only after a factual showing establishes the actual scope of that ruling, can Defendants even
20 raise the res judicata defense. The factual issues surrounding the scope of the Alpharma ruling are all
21 the more significant in light of the fact that the very same Court, just months later, denied summary
22 judgment on the very same defense, showing a clear understanding on the part of the Court that Section
23 12601 is not meant to act as an exemption for all FDA-approved pharmaceuticals as Defendants herein
24 allege. Defendants will have to introduce extrinsic evidence to justify their improbable position. Of
25 course, they will have to file their Answer first.

26 **2. Defendants Cannot Establish Privity between the AG in the Alpharma Case**
27 **and the Plaintiffs Herein**

28 A party cannot assert a prior adjudication against another who was not a party or in privity with
29 a party to the prior action.¹⁵ Privity is an elastic concept, and essentially reflects a conclusion that
30 collateral estoppel should be applied in a given case. *Id.* Though Defendants rely on general notions of
31 res judicata, they ignore the California law most on point – cases refusing to give res judicata effect to
32 prior Attorney General actions, where the party to be estopped in subsequent litigation is suing under

14 Nakash at 67 citing Neil Norman, Ltd v. William Kasper & Co. (1983) 149 Cal.App.3d 942, 948.

15 Lynch v. Glass (1975) 44 Cal.App.3d 943, 947.

1 statutory “private attorney general” status. California courts have held that private litigants bringing
2 such actions are not bound by the results of prior actions brought by the AG.

3 In Payne v. National Collection Systems, Inc. (2001) 91 Cal.App.4th 1037, 1044-1045, the court
4 rejected the argument that a prior action by the AG under B&P §§17200 and 17500 barred a subsequent
5 action by private litigants, even where, unlike here, the subsequent litigation arose from circumstances
6 and conduct identical to the prior AG action. The AG brought an action against an airline carrier and a
7 credit and collections agency, alleging the two defendants violated the UCL by operating a “job training
8 program” which defrauded low-income applicants out of their tuition. After the court entered a
9 permanent injunction and awarded penalties and restitution, a subsequent action was brought by private
10 litigants seeking restitution based on the same conduct. The court declined to bar the subsequent action,
11 because consumer protection actions brought by the AG, seeking injunctive relief, civil penalties and
12 restitution, do not require the same safeguards to protect a defendant from multiple suits, one of the
13 primary purposes for applying res judicata. Payne, *supra*, 91 Cal.App.4th at p. 1045.

14 In reaching its conclusion, the Payne court relied on the Supreme Court’s decision in People v.
15 Pacific Land Research Co. (1977) 20 Cal.3d 10, and held “because of the California Supreme Court’s
16 determination that res judicata effect is not to be accorded to a judgment in an unlawful competition
17 lawsuit commenced by a prosecutor in a subsequent lawsuit by persons defrauded by a defendant, the
18 provisions of section 41 of the Restatement Second of Judgments have no application to this case.”¹⁶
19 The cited section of the Restatement provides for binding persons not present in prior litigation to the
20 result thereof if their interests were “represented” in the prior litigation by “[a]n official or agency
21 invested by law with authority to represent the person’s interests,” precisely the argument which is
22 proposed by Defendants here. *Id.*, fn. 2.

23 California courts have not stopped at section 17200 in their refusal to find privity between the
24 Attorney General and private litigants authorized to sue for the public benefit. Both the Attorney
25 General and private citizens serving as trustees of charitable corporations have standing to sue to ensure
26 that assets held by a charitable corporation are used for charitable purposes.¹⁷ Although both have
27 standing to sue for breach of a charitable trust, and both would be suing for the same purpose, i.e., to
28 protect the beneficiaries of the charitable trust, nevertheless there is no privity between the AG and
29

30 ¹⁶Payne, *supra*, at p. 1047.

31 ¹⁷Holt v. College of Osteopathic Physicians and Surgeons (1964) 61 Cal.2d 750, 752-753 (minority
32 trustees of a charitable corporation can sue the majority trustees to enjoin their wrongful diversion of
corporate assets in breach of a trust for charitable purposes); Corp. Code §§ 5142.

1 trustees of the charitable corporation that would bar a subsequent suit for breach of charitable trust.¹⁸
2 Contrary to Defendants’ claim, the mere fact both the private individuals and the AG are suing to
3 protect the same public interest does not place them in privity.

4 Defendants cannot avoid application of Payne to this case. Plaintiffs here are asserting a cause of
5 action for restitution under section 17200, and to this extent Payne is directly on point and
6 indistinguishable. Moreover, Payne’s more fundamental holding that the AG is not in privity with
7 private litigants suing under “private attorney general” statutes, such as section 17200 (and by
8 implication, Proposition 65), defeats the defendant’s contentions in their entirety.

9 **3. The Issues Presented in the Alpharma Case Are not Identical to the Issues
10 Presented Here**

11 Defendants focus entirely on the fact they are raising a defense based on the same regulation
12 raised in Alpharma, CCR § 12601(b)(2), and ignore the glaring distinction between the products at
13 issue. Unless the issue or cause of action in the two actions is *identical*, the first judgment *cannot* act to
14 bar the second suit.¹⁹ The complete lack of identity between the products at issue – in the Alpharma
15 case, prescription shampoo with FDA-labeling containing a carcinogenicity warning, and in this action,
16 thimerosal and thimerosal-containing vaccines without any warning, is an insurmountable barrier to
17 applying res judicata.²⁰

18 In Younger v. Jensen (1980) 26 Cal.3d 397, the California Supreme Court found prior litigation
19 pursued by the Attorney General could not be raised as a bar to subsequent litigation involving events
20 and transactions “separable” from the prior litigation, even if the events at issue in the subsequent
21 litigation were “identical” to the prior events. The court explained:

22 ***[I]f the relevant facts in the two cases are separable, even though they be similar or identical,***
23 ***collateral estoppel does not govern the legal issues which recur in the second case. . . ., the***
24 ***legal matter raised in the second proceeding must involve the same set of events or documents***
and the same bundle of legal principles that contributed to the rendering of the first judgment.
[Citations.]” (Fn. omitted.) Younger v. Jensen, *supra*, 26 Cal.3d at pp. 412-413.

25
26 ¹⁸Los Angeles County Pioneer Society v. Historical Society of Southern Calif. (1953) 40 Cal.2d
27 852, 857.

28 ¹⁹Agarwal v. Johnson (1979) 25 Cal. 3rd 932, 954; *see also*, Gates v. Superior Court (1986) 178
29 Cal.App.3d 301, 310-311; Citizens for Open Access to Sand and Tide, Inc. v. Seadrift Assoc. (1998) 60
30 Cal.App.4th 1053, 1068.

31 ²⁰Furthermore, the entire record of the Alpharma case is not before this Court. However, as noted
32 herein, even if those records were before this Court, it is clear from the same Court’s ruling in the Baxter
case that its decision in Alpharma was based on the facts of that case – facts which are *not* present here.
In Baxter, with facts similar to the instant case, namely, the lack of warning in the FDA-approved labeling,
Judge Garcia denied Baxter the protections of Section 12601. If anything, the Baxter decision can equally
be argued to be a res judicata bar to Defendants raising their Section 12601 defense in this case.

1 Here Defendants cannot hope to satisfy this Supreme Court directive. The events and
2 transactions at issue here, the manufacture, distribution, sale and injection of thimerosal into children
3 via vaccination in the absence of warning, are clearly separable from the events in the Alpharma
4 litigation – the sale and distribution of prescription shampoo with specific carcinogenesis warnings
5 inside of FDA-approved labeling. The mere coincidence of the similarity of defenses presented in both
6 actions does not render these distinct events inseparable.

7 4. The Cases to which Defendants Cite Are Unavailing

8 The cases relied upon by Defendants are either wholly distinguishable or wholly supportive of
9 Plaintiffs’ position. Defendants rely primarily on Rysenburger v. Dairymen’s Fertilizer Cooperative,
10 Inc. (1968) 266 Cal.App.2d 269, for the general proposition that res judicata effect should be given to
11 judgments rendered in any case where statutory authority to pursue such claims has been given to a
12 public entity (Demurrer, p. 7:9-12). As seen above, this general statement is not universally true;
13 actions by the AG do not preclude subsequent actions where private individuals have *also* been given
14 statutory authority to pursue actions to protect the public interest.²¹ In Rysenburger, and in Citizens for
15 Open Access, *supra*, there was ***no statutory authority*** which granted both the public entity ***and*** private
16 litigants standing to sue for transgressions against the public interest. Here, by contrast, and in cases
17 cited by Plaintiffs refusing to find privity between the AG and private litigants (Payne, Pioneer Society),
18 statutory authority to pursue actions to protect the public interest is ***shared*** by both the AG and private
19 litigants. Defendants have not, and cannot, cite to a single case where a private litigant suing as a
20 “private attorney general” was barred by a prior AG action.

21 Further, a common factor in both Rysenburger and Citizens for Open Access which supported a
22 finding of collateral estoppel, and which is glaringly absent here, is the identity of the issues and
23 commonality of the subject matter of the litigation. As noted above, collateral estoppel cannot be
24 applied to subsequent litigation involving different events and transactions.²² Rysenburger and Citizens
25 for Open Access did not run afoul of this rule. In both of those cases, the subject matter of the prior and
26 subsequent litigation were *identical* – use of a common parcel of land. In Rysenburger, plaintiffs sought
27 to re-litigate whether defendant’s operation of a fertilizer plant was a nuisance; in Citizens for Open
28 Access, the plaintiffs sought to re-litigate public access to the same strip of coastal property as the prior
29 litigation. Such circumstances stand in stark contrast to the divergent products at issue here and in the
30 Alpharma litigation – thimerosal-containing vaccines vs. prescription shampoo where the former has

31
32 ²¹Payne, *supra*, 91 Cal.App.4th at 1044-1045, Pioneer Society, *supra*, 40 Cal.2d at 857.

²²Younger v. Jensen, *supra*, 26 Cal.3d at pp. 412-413.

1 no reproductive and/or developmental toxicity warning in its FDA labeling regarding the subject toxin
2 and the latter had a 4 paragraph carcinogenicity warning in its FDA labeling the subject toxin.

3 Furthermore, Plaintiffs here had no control or participation in the prior AG action, and hence
4 could not have expected to be bound by any judgment in that action. This rule was applied in Lynch v.
5 Glass, supra, 44 Cal.App.3d at p. 949, a case cited by Defendants but which directly supports the
6 Plaintiffs. Participation and control of the litigation, and a corresponding expectation to be bound, was
7 present in Rysenburger, where the court applied collateral estoppel against private plaintiffs that had
8 urged the municipalities to file suit against the defendant, and had performed “90% of the work” which
9 was simply handed over to the municipalities for use in their suit.²³ By contrast, participation and
10 control in the prior litigation was absent in Lynch v. Glass, and the court refused to apply collateral
11 estoppel against parties that had “no power to control any aspect of the case,” and could not reasonably
12 have expected to be bound by the prior litigation.²⁴ The instant Plaintiffs, suing to protect the interests
13 of children and parents exposed to thimerosal-containing vaccines without warning, had no
14 participation or control, and could have no expectation of being bound by, litigation brought by the AG
15 manufacturers and distributors of prescription shampoo.

16 **5. Even if All of the Elements of Res Judicata Are Applicable Here, the Court**
17 **Should Deny Application of the Doctrine Because It Will Result in Injustice**
18 **and Also Because Relitigation Would Serve the Public Interest**

18 Even if, *arguendo*, Defendants had met all of the elements of res judicata, this case is precisely
19 the type of situation in which the public interest exception to the application of claim preclusion should
20 be invoked. The California Supreme Court has repeatedly held that res judicata will not be applied “if
21 injustice would result or if the public interest requires that relitigation not be foreclosed.”²⁵ Here, the
22 issues are of utmost public importance. If res judicata is applied, millions of California’s children and
23 adults will continue to endure unwarned exposures to mercury in vaccines because both citizen
24 enforcers and public prosecutors would be unable to enforce the mandate of Proposition 65.
25 Furthermore, any res judicata ruling by this Court would necessarily also mean that all plaintiffs are
26 forever barred from raising the issue of toxic exposure from a pharmaceutical, a result which is in direct
27 contradiction of the desires of the People of the State of California in enacting Proposition 65 and
28

29 ²³Rysenburger, supra, at p. 276.

30 ²⁴Lynch, supra, at p. 949.

31 ²⁵Arcadia Unified School Dist. v. State Dept. of Education (1992) 2 Cal.4th 251, 257; City of
32 Sacramento v. State of California (1990) 50 Cal.3d 51, 64; Consumers Lobby Against Monopolies v.
Public Utilities Com. (1979) 25 Cal.3d 891, 902.

1 certainly against the intent of OEHHA in drafting and adopting Section 12601(b)(2). This would be
2 manifestly unjust, and the public interest *does* require that Defendants be prevented from using the
3 Alpharma decision in order to invoke res judicata.

4 **III. PROPOSITION 65 IS NOT PREEMPTED BY “FEDERAL REGULATION” OF**
5 **VACCINES**

6 Defendants’ second argument is that the warnings required under Proposition 65 are preempted
7 by federal law. At pp. 8-18 of their memorandum, defendants point to a “comprehensive and distinctly
8 federal program for vaccines” they say preempts any warning requirement under Proposition 65.
9 Defendants never actually identify any particular statute or regulation that they claim preempts
10 Proposition 65 here; rather, they simply insist that preemption necessarily flows from the extensiveness
11 of federal regulation of vaccines.

12 But preemption is the exception, not the rule. Preemption is not a hovering omnipresence, or
13 something derived from penumbras, or something to be inferred from the presence even of detailed
14 federal statutory regimes. When defendants’ rhetoric is boiled away, there is, again, not a single statute
15 or regulation that is actually asserted to have preemptive force. Nor do defendants cite a single case,
16 from California or anywhere else, in which any federal law has been held to preempt the state warnings
17 required by Proposition 65 in this situation. The statute in fact fits comfortably within the established
18 presumption against preemption.

19 **A. PROPOSITION 65 IS PRESUMED TO BE FREE FROM PREEMPTION**

20 There is no doubt that under the “Supremacy Clause” of the U.S. Constitution, Congress has the
21 power to preempt state laws. It is “equally well established,” however, that preemption analysis,
22 “starts with the assumption that the historic police powers of the States [are] not to be superseded by
23 ...Federal Act unless that [is] the clear and manifest purpose of Congress.”²⁶

24 This Court’s analysis of defendants’ assertions is “informed by two presumptions about the
25 nature of preemption.” First, Congress does not “cavalierly preempt state-law causes of action.”²⁷ This
26 presumption applies with particular force in matters of public health and safety, which are “primarily,
27 and historically, a matter of local concern[.]” Hillsborough County v. Automated Med. Labs, 471 U.S.
28 707, 719 (1985), and is “consistent with both federalism concerns and the historic primary of state
29 regulation of matters of health and safety.” Medtronic, supra, at 485. Proposition 65, directed as it is to

31 ²⁶Dowhal v. Smithkline Beecham Consumer Healthcare, 122 Cal. Rptr. 246, 252 (2002), quoting
32 Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992).

²⁷Medtronic, Inc. v. Lohr, 518 U.S. 470, 484-85 (1996).

1 the People’s health and safety, enjoys these established presumptions.²⁸ Second, “the purpose of
2 Congress is the ultimate touchstone” in any preemption analysis.” Medtronic, at 485.

3 **B. THERE IS NO EXPRESS PREEMPTION**

4 Defendants do not argue that any statute expressly preempts Proposition 65. The absence of any
5 such explicit preemption provision is itself significant.

6 Congress has included express preemption provisions in some parts of the Food, Drug and
7 Cosmetic Act, but never has extended such provision to the FDCA as a whole. For medical devices,
8 specific FDA requirements for particular devices expressly preempt state laws applicable to the same
9 device. 21 U.S.C. §360k(a) (Medical Device Amendments of 1976). In 1990, the Nutrition Labeling
10 and Education Act amended the FDCA, and expressly preempted certain state requirements concerning
11 nutritional labeling. (21 U.S.C. §343-1. Most recently, in the Food and Drug Administration
12 Modernization Act of 1997, the FDCA was amended to preempt certain state requirements for
13 nonprescription, or “over-the-counter, drugs. 21 U.S.C. §379r(a). Similarly, the 1997 law preempts
14 certain state requirements for cosmetics. 21 U.S.C. §379s(a), id., 111 Stat. 2376. Among the many
15 foods, drugs, and cosmetics regulated by the FDCA, Congress has chosen specific categories of
16 products with respect to which it has selectively adopted differing, and sometimes quite narrow,
17 preemptions provision. *No such preemption has ever been afforded to prescription drugs or vaccines.*

18 Moreover, when Congress has imposed preemption, it has expressly *exempted* laws such as
19 Proposition 65. The preemption provision of the Nutrition Labeling and Education Act of 1990 does
20 not apply to any requirement “respecting a statement in the labeling of food that provides for a warning
21 concerning the safety of the food or a component of the food.” The 1997 Modernization Act, while
22 preempting some state laws concerning nonprescription drugs, specifically exempts from those
23 provisions any state law passed by initiative or referendum prior to September 1, 1997.

24 In sum, Congress has never preempted laws relating to drugs generally. In the few instances in
25 which Congress has imposed preemption, it has avoided preemption of laws such as Proposition 65.
26 And when an express preemption provision does exist, it may be inferred that Congress did not intend
27
28
29

30 ²⁸Committee of Dental Amalgam Mfrs. v. Stratton, 92 F.3d 807 (9th Cir. 1996), cert. denied, 519
31 U.S. 1084 (1997); Chemical Specialties Mfs. Ass’n v. Allenby, 958 F.2d 941, 943 (9th Cir. 1992), cert.
32 denied, 506 U.S. 825 (1993). *See also* People ex rel. Lungren v. Cotter, 53 Cal. App. 4th 1373, 1381 (1997)
(even where an express preemption provision exists, a court “must narrowly read the preemption clause
because Proposition 65 is an instance of the state exercising its police power.” (*citing Medtronic, supra,*
and Ketchum v. Hyunda; Motor Co., 49 Cal. App. 4th 1672, 1678 (1996))).

1 any further *implied* preemption.²⁹ It is thus fair to assume that Congress did not intend to preempt the
2 operation of Proposition 65 in the circumstances of this case.

3 Seeking somehow to turn this established inference on its head, defendants attempt to
4 distinguish the obviously persuasive case of Committee of Dental Amalgam Mfrs. and Distributors v.
5 Stratton, 92 F.3d 807 (1996), on the basis that that case involved an express preemption provision,
6 whereas here the FDA has “taken a very active role” in regulating vaccines. Memorandum at 18.
7 Stratton held that the express preemption provisions of the Medical Devices Act do not preempt
8 Proposition 65 warnings with regard to dental amalgam. Despite some highly creative spinning,
9 however, Stratton plainly supports the People here -- because if Proposition 65 claims were not
10 preempted even by an express preemption provision, surely there can be no implied preemption where
11 Congress has chosen not to expressly preempt at all.

12 C. THERE IS NO IMPLIED PREEMPTION

13 Aside from express preemption, state law can be preempted in two ways. If Congress evinces an
14 intent to fully occupy a given field, state laws falling within it are preempted. Alternatively, state law may
15 still be preempted to the extent that it actually conflicts with federal law, i.e., it is impossible to comply with
16 both state and federal law, or if state law stands as an obstacle to the accomplishment of the full purposes
17 of the objectives of Congress.³⁰ The conflict between state and federal law, however, must be real and
18 irreconcilable.³¹

19 1. No Statute Occupies the Field of Vaccine Warnings

20 It is unclear whether defendants are actually asserting that Congress has “occupied the field” of
21 vaccine regulation sufficiently to bar plaintiffs’ claims here by means of “field preemption.” While
22 most of defendants’ argument is framed in terms of conflict preemption, and while they never precisely
23 indicate whether it is the FDCA, or the National Vaccine Injury Compensation Program, or even some
24 other law that is preemptive, defendants’ repeated insistence that “comprehensive” federal regulation is
25 pervasive -- as in the assertion at p. 9 that such regulation “leaves no room” for Proposition 65 -- might
26 be read as an argument about “field preemption.” Any such argument is meritless.

27 The Supreme Court has made it very clear that “comprehensive” regulation, even if established,
28

29 ²⁹Cipollone, supra, 505 U.S. at 517; see also Sprietsma v. Mercury Marine, 123 S.Ct. 518, 530
30 (2002) (express preemption provisions of the Federal Boat Safety Act that arguably covered state statutes,
31 but not common law actions, suggested Congress’ intent not to impliedly preempt the latter either).

32 ³⁰Silkwood v. Kerr-McGee Corp. (1984) 464 U.S. 238, 248.

³¹ Florida Lime and Avocado Growers v. Paul, (1963) 373 U.S. 133, 141, 146.

1 does not equate to preemption:

2 We are even more reluctant to infer pre-emption from the comprehensiveness of regulations
3 than from the comprehensiveness of statutes. As a result of their specialized functions, agencies
4 normally deal with problems in far more detail than does Congress. To infer pre-emption
5 whenever an agency deals with a problem comprehensively is virtually tantamount to saying that
6 whenever a federal agency decides to step into a field, its regulations will be exclusive. Such a
7 rule, of course, would be inconsistent with the federal-state balance embodied in our Supremacy
8 Clause jurisprudence. Hillsborough, *supra*, 471 U.S. at 717.

9 Or as the California Supreme Court straightforwardly put it, “[t]he fact that the pharmaceutical
10 industry is highly regulated does not distinguish it from numerous other industries.”³² Defendants’ long
11 description of the FDA approval process is thus beside the point. Defendants certainly cite no case
12 holding that the federal government’s extensive involvement in vaccine issues automatically translates
13 into preemption of laws like Proposition 65. In a recent and exhaustive survey, one of the nation’s
14 leading authorities on products liability and toxic torts came to this conclusion about preemption in
15 pharmaceutical cases:

16 In the realm of pharmaceuticals, the FDCA contains no language expressly preempting claims
17 brought under state law. Moreover, courts considering the issue have held generally that with
18 regard to health and safety issues, the statutory language does not evince a congressional
19 objective to so occupy the field of pharmaceutical regulation as to impliedly preempt state
20 claims.³³

21 Nor is there any field preemption under the NVICP. Although defendants very disingenuously
22 quote from Hurley v. Lederle Labs, 863 F.2d 1173, 1179 (5th Cir. 1989) at p. 11 of their memorandum,
23 the actual holding of Hurley is that the Vaccine Act is “proof that Congress intends no preemption of
24 the state law liability of vaccine manufacturers. The NCVI Act clearly states that state law remedies
25 apply to the manufacture and sale of vaccines and it even makes recovery easier for injured consumers.”
26 *Id.* at 1178. After a thorough survey of the FDCA, and of the Public Health Service Act and its
27 amendments as well, the Fifth Circuit concluded in Hurley that “it is possible to construct sound policy
28 arguments in favor of preemption in this case, but there is virtually no indication in the relevant law that
29 Congress or the FDA explicitly or implicitly accepted them.” *Id.*

30 Finally, defendants repeatedly invoke a need for “uniformity.” Just such a concern was also
31 invoked by defendant in the most recent Supreme Court preemption case, Sprietsma, *supra*. Yet the
32 Court held that even where there was an express preemption clause, “the concern with uniformity does
33 not justify the displacement of state common-law remedies that compensate accident victims and their
34 families and that serve the Act’s more prominent objective, emphasized by its title, of promoting

31 ³²Carlin v. Superior Court, 13 Cal. 4th 1104, 1115 n.4 (1996).

32 ³³M. Stuart Madden, Federal Preemption of Inconsistent Safety Obligations, 21 Pace L.Rev. 103,
138-39 (2000) (footnotes omitted).

1 boating safety.” 123 S.Ct.at 530.

2 2. There is No Conflict Preemption

3 Proposition 65 does not conflict with any federal provision relating to vaccines, for the simple,
4 fundamental reason that FDA regulations regarding the design of, and warnings about, prescription
5 drugs are minimum standards only. A state is free to impose different or higher standards. That is what
6 Proposition 65 does concerning the high levels of mercury in vaccines.

7 In Carlin, supra, the California Supreme Court noted that, “[a]s numerous courts have
8 concluded, Congress evinced no intention of preempting state tort liability for injuries from prescription
9 drugs.” (citations omitted). Carlin, supra, 13 Cal. 4th at 1113-14. More recently, the United States
10 District Court for the Central District of California surveyed the law and found “not a single case
11 holding that FDA prescription drug requirements preempted state law claims:”

12 As plaintiff correctly argues, most courts have found that FDA regulations as to design and
13 warning standards are minimum standards which do not preempt state law defective design and
14 failure to warn claims. *See, e.g., Hill v. Searle Labs.*, 884 F.2d 1064, 1068 (8th Cir.1989) (“FDA
15 approval is not a shield to liability ... FDA regulations are generally minimum standards of
16 conduct unless Congress intended to preempt common law, which Congress has not done in this
17 area.”); *Kociemba v. Searle & Co.*, 680 F.Supp. 1293, 1299 (D.Minn.1988) (“The mere fact that
18 the Cu-7 received FDA approval does not, by itself, indicate that Congress impliedly intended to
19 preclude state tort actions against prescription drug manufacturers. This is especially true in light
20 of the widely held view that FDA regulation of prescription drugs establishes minimum
21 standards, both as to design and warning,” citing *Graham v. Wyeth Labs.*, 666 F.Supp. 1483
(D.Kan.1987), *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652 (1st Cir.1981) and *Salmon
v. Parke Davis & Co.*, 520 F.2d 1359 (4th Cir.1975)); *Mazur v. Merck & Co.*, 742 F.Supp. 239,
247 (E.D.Pa.1990) (“mere compliance with FDA suggestion, or for that matter, regulation or
order, does not mean that state tort law becomes irrelevant...[C]ompliance with an FDA
regulation may establish that the manufacturer met the appropriate minimum standards of due
care, but compliance does not necessarily absolve the manufacturer of all liability ...
Manufacturers must meet state safety requirements, whether codified or embodied in the
common law, in addition to satisfying initial FDA requirements”). Indeed, Pfizer cites not a
single case holding that FDA prescription drug requirements preempted state law claims.

22 Motus v. Pfizer Inc., 127 F.Supp.2d 1085, 1092 (C.D. Cal. 2000).

23 Defendants simply cannot demonstrate an actual, irreconcilable conflict between Proposition 65
24 and the FDCA or the Vaccine Act.³⁴ Proposition 65 does not require the warning to be provided on a
25 label, but allows it through pharmacists, other material, or through doctors. Proposition 65’s
26 implementing regulations specifically allow warnings to be given in forms other than labeling. See 22
27 CCR §12601(b)(1)(B). As a result, it has been upheld even as against express preemption provisions.
28 Allenby, supra, 958 F.2d at 948; Stratton, supra, 92 F.3d at 810. Warnings may be provided through
29 placards or signs posted in doctor’s offices, or through doctors themselves. The Court of Appeal
30 specifically has held that “‘for purposes of preemption analysis,’ the party arguing preemption must
31

32 ³⁴ The immense footnote 9 at p. 10 of defendants’ memorandum, with its 19 case citations, is irrelevant for
the obvious reason that the NVICP applies only to recipients of a vaccine and not to the State. Defendants
concede as much in the last paragraph of the footnote.

1 show ‘a physical impossibility of complying’ with both Proposition 65 and the federal statute ‘before
2 succeeding on a claim that Proposition 65 is preempted on this theory.’” Cotter, supra, 53 Cal.App. 4th
3 at 1394, quoting Allenby, supra, 958 F.2d at 948-49, and holding that Proposition 65 claims were not
4 preempted by the express preemption provision of the Federal Hazardous Substances Act.

5 **3. Proposition 65 Is Not an Obstacle to the Accomplishment of the Goals of the**
6 **FDCA**

7 Defendants argue that Proposition 65 is contrary to FDA’s policy disfavoring unnecessary and
8 inappropriate warnings. While such a policy sounds laudable, nothing indicates that Proposition 65 is
9 contrary to such a policy, or that the FDA views it as such. Moreover, there is certainly no evidence
10 that Proposition 65 would lead to a proliferation of unnecessary warnings for prescription drugs. As the
11 Court of Appeal noted in Ingredient Communication Council v. Lungren (1992) 4 Cal.App.4th 1480,
12 1494, n. 8:

13 “The threshold risk under Proposition 65 is not especially low compared to other
14 epidemiological standards commonly used by regulatory bodies. Some agencies of the federal
15 government, for example, restrict carcinogens if they cause one additional case of cancer per
16 million people exposed over a lifetime. Under Proposition 65, warnings are required if 1
17 additional case of cancer per 100,000 people can be expected.”

18 **D. DEFENDANTS’ AUTHORITIES ARE INAPPOSITE**

19 At page 12 of their memorandum, defendants cite several cases for the broad proposition that
20 “[c]ourts have held that comprehensive federal labeling laws preempt state law concerning labeling for
21 federally-regulated products.” But none of these authorities remotely supports their position here.
22 Kanter v. Warner-Lambert Co., 99 Cal.App. 4th 780(2002) dealt not with conflict preemption, as
23 defendants say, but with express preemption. *Id.* at 789-90. *See also* page 797(“Our conclusion that all
24 of plaintiffs’ state law claims are expressly preempted by §379r(a) makes it unnecessary to consider the
25 theory of conflict preemption....”). Cipollone, supra, also dealt with an express preemption provision
26 quoted by defendants in their description of the case.

27 Buckman v. Plaintiff’s Legal Committee, 531 U.S. 341 (2001) is irrelevant because the People
28 make no claims concerning any misrepresentations to the FDA. Plaintiffs’ claims here center only on
29 the warning required by the State, and not on any interaction between defendants and the FDA. Finally,
30 the New Jersey Supreme Court in R.F. v. Abbott Labs., 745 A.2d 1174 (N.J. 2000) *distinguished* its
31 earlier decision in Feldman v. Lederle Labs., 592 A.2d 1176 (N.J. 1996). Feldman held that there is no
32 implied preemption under the FDCA of state law claims concerning prescription drugs. R.F. was
explicitly limited to the unique context of the HIV screening test and the FDA’s directives to its
manufacturer during the early “national crisis” posed by AIDS. *Id.* at 1197.

None of these authorities is similar to the present case at all. Perhaps recognizing this,

1 defendants also rely on an amicus brief from the FDA in Dowhal, *supra*. Leaving aside the fact that the
2 FDA’s position was rejected by the Court of Appeal, the amicus brief in Dowhal was clearly a product
3 of the unique history of that case, in which the FDA had repeatedly “hindered” the defendants’ attempts
4 to comply with their labeling obligations. In fact, the Court of Appeal acknowledged that “respondents’
5 attempts to comply with their state obligations under Proposition 65 have been hindered by a federal
6 bureaucracy that, at least since...the Modernization Act of 1997, was either unwilling or unable to
7 recognize the limited scope of its authority.” *Id.*, 122 Cal.Rptr. at 257. In sum, defendants simply can
8 cite no precedent that Proposition 65 claims regarding prescription drugs are preempted in this context,
9 and indeed can cite no precedent that state law claims of any kind are preempted in this area. Given the
10 “historic presumption” against preemption here, defendants have failed to satisfy their burden at the
11 demurrer stage.

12 **IV. PLAINTIFFS’ 60-DAY NOTICE IS MORE THAN ADEQUATE TO MEET THE**
13 **STANDARDS OF PROPOSITION 65**³⁵

14 **A. PLAINTIFFS’ NOTICE NEED NOT INCLUDE A CERTIFICATE OF MERIT**

15 SB 471 was signed into law by the Governor on October 7, 2001. The statute went into effect
16 on January 1, 2002. One of the main drafters and proponents of SB 471 was the California AG, much
17 of it through the participation of Deputy AG Edward Weil. Most relevant to Defendants’ Demurrer is
18 SB 471’s requirement that Plaintiffs serve a certificate of merit along with any 60-day notice which they
19 serve. Defendants’ interpretation of the statute not only defies logic, but would lead to an absurd result
20 expressly going against the statutory interpretation of the Attorney General. This aside, the Defendants’
21 position goes against applicable law on statutory interpretation.

22 **1. The California Attorney General Has Issued an Opinion Letter Regarding
the Applicability of SB 471**

23 Conspicuously absent from Defendants’ brief is the AG’s opinion letter on SB 471. On
24 December 21, 2001, in response to a number of inquiries, the AG through Mr. Weil, issued an opinion
25 letter regarding the amendments to Proposition 65. The AG’s opinion in this case is of particular
26 importance and should be given great weight by this Court. Not only was the AG instrumental in the
27 drafting and passage of the amendments to Proposition 65, but the AG is the top enforcement official
28 with respect to Proposition 65 and is and has been extremely active in and intimately familiar with
29 Proposition 65 litigation.

30 _____
31 ³⁵Defendants concede that Plaintiffs have complied with all aspects of Section 12903 with the
32 exception of Section 12903(b)(2)(D) and (E). Plaintiffs do not dispute that they did not comply with
Section 12903(b)(2)(E), but contend that they need not do so, and even if this Court were to hold that such
compliance was necessary, it would only act to exclude, from the Proposition 65 cause of action *only*,
exposures to U.S. military personnel.

1 In his letter, Mr. Weil provides a detailed analysis of the applicability of various portions of the
2 amendments, including, among other things, the certificate of merit requirement. First, and foremost,
3 Mr. Weil demonstrates that the amendments were not meant to be retroactive. Second, he concludes
4 that the requirement of a certificate of merit on pre-2002 notices would amount to a retroactive
5 application of the amendments.³⁶

6 2. The Attorney General's Opinion Is Consistent with the Law

7 Plaintiffs' 60-day notices were served on November 19, 2001, before the effective date of SB
8 471. Defendants incorrectly attempt to read SB 471 to apply to all lawsuits filed after January 1, 2002.
9 Contrary to Defendants' assertion, the application of the certificate of merit requirement to pre-2002 60-
10 day notices necessarily would be a retroactive application.

11 a. SB 471 Is not Retroactive

12 The general rule is that "statutes do not operate retrospectively unless the Legislature plainly
13 intended them to do so."³⁷ However, where an amendment merely *clarifies* existing law, it may be
14 given retroactive effect even without an expression of legislative intent for retroactivity.³⁸ There is
15 nothing in SB 471 that plainly states that it is applicable retroactively; nor is there any legislative intent
16 to apply the amendments retroactively. Furthermore, SB 471 adds new requirements for a Proposition
17 65 action, among them the requirement that a certificate of merit accompany certain 60-day notices of
18 violation. These are clearly new requirements and not clarifications of the then existing law. Therefore,
19 SB 471 cannot be given retroactive effect.

20 b. The Act Triggering the Certificate of Merit Requirement Is the Sending of a 21 60-notice, Not the Filing of a Lawsuit

22 The statute as amended reads "[i]f the notice alleges a violation of section 25249.6, the notice of
23 alleged violation shall include a certificate of merit . . ." H&S 25249.7(d)(1). Therefore, contrary to
24 Defendants' assertion, the act triggering the duty to provide a certificate of merit is the sending of a 60-
25 day notice, *not* the filing of a lawsuit. As such, any requirement that a pre-2002 notice contain a
26 certificate of merit would necessarily amount to retroactive application of SB 471.³⁹

27 In his letter, Mr. Weil also disposes of the very same argument that Defendants make here. He
28 states that:

29 "[w]e recognize that the statute states that 'actions pursuant to this section may be brought by

30 ³⁶See Pages 1 and 2 of Letter dated December 21, 2001 from Edward G. Weil, Esq. to John Dittoe
31 and Nadia Bishop attached to the Khorrami Dec. as Exhibit "G." (Hereinafter "AG Letter").

32 ³⁷Western Sec. Bank v. Superior Court (1997) 15 Cal. 4th 232, 243; *see also*, Evangelatos v.
Superior Court (1988) 44 Cal. 3d 1188.

³⁸Negrette v. California State Lottery Comm. (1994) 21 Cal. App. 4th 1739, 1744.

³⁹*See also*, AG Letter at page 2.

1 any person in the public interest if both of the following requirements are met.’ Thus, the
2 section could be read to apply to any ‘action brought’ on or after January 1, 2002. This
3 construction, however, would mean that sixty-notices given as early as November 1, 2001 would
4 have been required to include the certificate of merit, essentially requiring compliance with the
5 new provision for notices given before the statute took effect. Put another way, a notice that was
6 entirely valid when given prior to January 1, 2002, would retroactively be invalidated on the
7 effective date of SB 471. This would mean that the amendments had changed ‘the legal
8 consequences of an act *completed* before the effective date of the statute’ under Florence
9 Western Medical Clinic v. Bonta, [(2000) 77 cal. App. 4th 493,] 503, and therefore is
10 retroactive.”

11 **3. Application of SB 471 to pre-2002 notices would necessarily be a retroactive**
12 **application**

13 Defendants’ position is that application of SB 471 to pre-2002 notices would not be a retroactive
14 application. In support of their position, Defendants argue that SB 471 states that no complaint may be
15 filed unless: 1) a 60-day notice is served; and 2) a certificate of merit is served; and 3) no public
16 prosecutor is pursuing the case upon the expiration of the 60-day period. This is clearly erroneous
17 because the law states that no lawsuit may be filed unless two – *not three* – conditions are met: 1) a 60-
18 day notice is served; and 2) no public prosecutor is pursuing the case upon the expiration of the 60-day
19 period. All that is required to file a complaint is a legally sufficient 60-day notice. And SB 471
20 changed what constitutes a legally sufficient notice, but only after January 1, 2002.

21 This is completely consistent with the AG’s Opinion letter. As the AG points out, “[t]he act
22 triggering the duty to provide a certificate of merit is the giving of a notice of violation. Thus, a legally
23 sufficient notice given prior to January 1, 2002, is not required to include a certificate of merit.”⁴⁰
24 Therefore, the certificate of merit requirement attaches to a notice and the definition of what is a legally
25 sufficient notice.

26 Here, there is no dispute that, at the time that Plaintiffs’ notices were served, H&S §25249.7(d)
27 *did not require* that a legally sufficient notice include a certificate of merit. Therefore, Defendants
28 received a legally sufficient 60-day notice on or about November 19, 2001, and one of the 2 prongs of
29 section 25249.7(d) were met. After the expiration of the 60-day period, the second prong was met – no
30 public prosecutors were pursuing the matter. Plaintiffs, therefore, were entitled to file suit.

31 **4. Defendants’ Argument for the Retroactive Application of SB 471 is meritless**

32 Defendants’ argument that the Court should apply SB 471 retroactively is misguided. They
primarily rely on Casey v. Katz, a 50 year old decision that is unavailing. While Defendants’ recitation
of the facts is correct, their attempt at analogizing that case misses the mark. Casey would be analogous
to this case would be if the plaintiff in that case had filed a claim, and thereafter, the law was changed
mandating that such claims include some additional information. In that situation, plaintiff would not

⁴⁰AG letter at 2.

1 have been required to file a second claim with the estate, but would have been entitled to file suit based
2 on his initial claim. Furthermore, despite the Casey Court's choice of words, Casey did not involve a
3 retroactive application of the law. "*There was no retroactive application* of section 707 in Casey v.
4 Katz."⁴¹

5 Here, the notice was sent out prior to the effective date of the statute in question. The statute
6 merely changed the definition of a legally sufficient notice to include some additional information,
7 namely, a certificate of merit. Defendants' interpretation is unlike the situation in Casey as it could
8 have only be accomplished by Plaintiffs including a certificate of merit prior to the effective date of the
9 statute, which would be a retroactive application. Defendants' interpretation would also invalidate all
10 pre-2002 notices on which a private plaintiff had not filed suit, even if such notices were sent prior to
11 any bill being introduced in the legislature and even if the parties had entered into a tolling agreement in
12 order to allow them to negotiate.

13 **5. Defendants' Interpretation of SB 471 Would Violate the Principle in Casey**
14 **and Also Would Lead to Absurd Results**

15 Indeed, Defendants' proposed interpretation, that the certificate of merit requirement attaches to
16 the lawsuit, and not the 60-day notice, is not only facially wrong, but would also lead to absurd results.
17 In the case of 60-day notices, a plaintiff can act on the notice well after 60 days has passed; the notice
18 does not become stale on the 61st day. Separately, it is quite typical for plaintiffs to serve a 60-day
19 notice and then engage in settlement negotiations with a defendant and refrain from filing suit in
20 exchange for a tolling agreement. After all, as Defendants have stressed, one of the interests being
21 served is the curing of the violation. Based on the complexity of the case and the number of parties,
22 such negotiations could take anywhere from months to a period of years.

23 According to Defendants' logic, all pre-2002 notices which are not stale, were instantaneously
24 invalidated on January 1, 2002. Even the most tortured reading of Casey would not allow for such a
25 result as it would deprive plaintiffs the right to address past wrongs and give all violating defendants a
26 windfall by allowing them to profit from their past illegal conduct. All the defendant would have to do
27 is to break off negotiations and argue that the plaintiff had not met the notice requirements thereby
28 avoiding years of liability. In fact, if Defendants' reasoning were correct, SB 471 would have to be
29 applied to all Proposition 65 cases which were filed prior to 2002. Certainly, it was not the intent of the
30 legislators, and definitely not that of the AG in drafting and supporting the legislation, to give violators

31 ⁴¹Halbert v. Berlinger (1954) 127 Cal. App. 2d 6, 14 (emphasis added). An example of the
32 situation in the Casey case would be in the amendments to the summary judgment statute extending the
notice period. While the amendment applied to pending cases, its application to such cases is *not*
retroactive.

1 a “get out of jail free” card.

2 **B. PLAINTIFFS’ NOTICE MORE THAN ADEQUATELY IDENTIFIES THE**
3 **PRODUCTS AT ISSUE**

4 **1. Plaintiffs’ Notices More than Meet the Standards of Section 12903(b)(2)(D)**

5 Defendants claim that the description of the products in question do not meet the standards of
6 Section 12903. At the outset, it is noteworthy that as Defendants concede, Section 12903 does *not*
7 require that Plaintiffs identify any products by name, by brand, or to provide any information regarding
8 a retailer, the date the product was purchased, any UPC or SKU number, “model or design number or
9 stock number or other more specific identification of products.” 22 CCR 12903(b)(2)(D) & (b)(4). Nor
10 does a 60-day notice need to provide the evidence Plaintiffs intend to use at trial or even the level of
11 exposure that is being alleged.⁴² Simply put, a 60-day notice is just that – a *notice*; it is not supposed to
12 contain every detail of a plaintiff’s case.

13 **a. Plaintiffs’ Method of Identifying the Subject Products Is Short, Concise, and**
14 **Encompasses All Offending Products without Being Overbroad**

15 Section 12903(b)(2)(D) requires that products be identified “sufficient to distinguish those
16 products or services from others sold or offered by the alleged violator for which no violation is
17 alleged.” Here, the only distinction between vaccine products that allegedly violate and those that
18 allegedly do not is the presence of mercury, primarily through the introduction of thimerosal, a mercury-
19 based product.

20 As Defendants, themselves are well aware, mercury and thimerosal do not willy nilly find their
21 way into vaccinations. To the contrary, Defendants intentionally include them in certain of their
22 vaccines. Therefore, Defendants are in the best position to know exactly which of their vaccinations
23 contain mercury and which do not. Each defendant should easily be able to compile a list of its
24 mercury-containing vaccinations by a simple database search.

25 **b. Plaintiffs’ Method of Identifying the Subject Products Is Superior to**
26 **Alternative Methods**

27 Other methods of identifying products would have been more problematic and confusing, lest
28 Defendants wish to claim that Plaintiffs must go beyond the explicit boundaries of Section 12903.
29 First, Section 12903 explicitly states that identifying products by name is not a necessity; that products
30 can be named by type.

31 Second, and perhaps more important, is the fact that this method is per se faulty as it is both
32 over-inclusive and under-inclusive at the same time. This is because the distinguishing characteristic
between vaccines that violate and those that do not is not whether the vaccine is for measles or the flu,

⁴²22 CCR 12903(b)(4)(b) and (c)

1 but whether the vaccine in question contains mercury. For example, if Plaintiffs identify a particular
2 vaccine product, any given defendant may have manufactured both mercury-containing and mercury-
3 free vaccinations either simultaneously or at different times during the subject period. As such, this
4 identification would necessarily be overbroad in the sense that it identifies products that do not contain
5 mercury; it is under-inclusive in the sense that it leaves out other vaccines that contain thimerosal, for
6 example, the measles vaccine. This would violate Section 12903(b)(2)(D) as outlined above.

7 This fact was not lost on OEHHA or industry. In fact, in the FSR for Section 12903, this was
8 one of the major topics of discussion. Commentator C-4 pointed out and OEHHA agreed that
9 “overbroad notices *diminish* the value of the notice to the prosecutor and *regulated entity*.” Plaintiffs
10 herein only take issue with the types of vaccines to which Defendants added mercury and/or mercury-
11 based thimerosal. Any other form of identification would be overbroad and under-inclusive.

12 Furthermore, identification of each type of vaccine that may contain mercury would add nothing
13 to the equation and would lead to a result that OEHHA specifically rejected. First, identification of all
14 types of vaccines that may contain mercury would do nothing to distinguish them from those that do not
15 contain mercury. Since the addition of mercury is still the distinguishing factor, the phrase of which
16 Defendants complain would still have to be included. Second, OEHHA specifically rejected this type of
17 notice because it would “create an issue concerning the information available to the noticing party at the
18 time of giving notice.” By this comment, OEHHA acknowledged that the noticing party necessarily
19 would not have all of the information necessary to identify with razor precision the entire gamut of
20 products that are violative. This was also the reason Section 12903 specifically does not require lot
21 numbers, UPC or SKU number, “model or design number or stock number or other more specific
22 identification of products.” In rejecting such specific product information, OEHHA acknowledged that
23 “[t]his type of information is not necessary to notify the alleged violator or public prosecutors of ‘the
24 violation which is the subject of the action,’ which is all that is required under the statute.”⁴³ OEHHA
25 also acknowledged that the list of items that are *not* necessary under 12903 is not all-inclusive, it is
26 merely illustrative.⁴⁴ This aside, Defendants’ position as to what the notice regulation requires does
27 nothing to allow Defendants or public prosecutors to distinguish the products that are allegedly
28 offending versus the ones that are not. In fact, it forces three outcomes, all of which defeat the purpose
29 of a 60-day notice: 1) it forces Plaintiffs to include products that they did not intend to include, namely

30
31 ⁴³FSR to Section 12903 at 16. The agency went on to note that “[i]dentification of specific codes
32 or product numbers would simply increase the possibility that products that clearly fall within a description
of the product in question might be excluded from an action simply because the business uses different
numbers for them, even though they are similar in all relevant characteristics.”

⁴⁴*Id.* at 17.

1 mercury-free vaccines; 2) it forces defendants to investigate products that were not even intended to be
2 part of the Proposition 65 case; and 3) it forces public prosecutors to investigate non-offending
3 products.

4 **2. The Court Should Evaluate Plaintiffs' Notice in Order to Effectuate the**
5 **Goals of the Statute and the 60-Day Notice Requirement, Not to Reward**
6 **Procedural Gamesmanship**

7 As Defendants admit, the 60-day notice requirement has a dual purpose: 1) to enable the public
8 prosecutor to intelligently decide whether to file suit; and 2) to provide the alleged violator with an
9 opportunity to cure the violation.⁴⁵ Here, the notices in question specify that they are directed at
10 vaccines that have mercury through the introduction of thimerosal. There is no other way to describe
11 the subject vaccines as any other descriptor would simply be superfluous and irrelevant to identifying
12 which vaccines are allegedly violative and which are not. Furthermore, mercury in vaccines has been
13 the subject of an immense public controversy. For example, in 1998, the FDA issued requests to all
14 vaccine manufacturers for them to disclose which of their vaccines contained thimerosal and which did
15 not. Until that date, even the FDA did not have a full account of the thimerosal content of vaccines.
16 Thereafter, there have been two separate sets of Congressional hearings. Moreover, prior to the
17 sending of the subject notices, there were already a number of personal injury and class action cases
18 pending in several states relating to mercury in vaccines.. It is 18 months since Defendants received
19 Plaintiffs' notice, they have made no attempt to discover the gamut of products covered by the notices.

20 No public prosecutor has objected in any way to Plaintiffs' notices. It is quite common for the
21 Attorney General's office to respond swiftly where it feels that a notice is inadequate and even where it
22 feels that a given plaintiff has not sufficiently investigated the claims. In fact, time and again, the
23 Attorney General has actively addressed inadequate and/or improperly investigated claims.⁴⁶ For
24 example, in his letter of July 18, 2002, Deputy Attorney General, Ed Weil, addresses certain notices
25 sent by a private plaintiff. Mr. Weil points out that the AG's office does not view the description of the
26 products in question to be adequate.⁴⁷ Similarly, in his January 22, 2002 letter to Reuben Yeroushalmi,
27 Mr. Weil, again, goes through, in detail the shortcomings of Mr. Yeroushalmi's notices relating to
28 Tresemme Color Creations and Color Generators. Mr. Weil points out inadequacies of the notices from
29 the identification of the chemicals, to the exposed population, to the person served. In 2002 alone, the
30 AG's office sent letters addressing the inadequacies of some 4,000 60-day notices, at least 3,500 of

31 ⁴⁵See e.g., FSR for Section 12903 at 3.

32 ⁴⁶See Letters from Deputy Attorney General to various plaintiffs attached as Exhibits "H" through
"R" to the Khorrami Dec.

⁴⁷See Letter dated July 18, 2002 from Deputy Attorney General, Ed Weil to Michael Stier attached
as Exhibit "O" to the Khorrami Dec.

1 which were served in 2001. Not surprisingly, Plaintiffs’ notice was not one of them.

2 Further, since even the most comprehensive notice is not going to contain all of the information
3 the AG needs to investigate, the AG commonly contacts plaintiffs and defendants alike and obtains
4 evidence and other information that he needs in order to decide how to deal with the subject action.⁴⁸
5 While the AG has spoken to Plaintiffs’ Counsel on a couple of occasions regarding the subject notice, at
6 no point has the AG expressed any issues with the adequacy of the subject notice, nor has the AG
7 undertaken his common practice of addressing any such inadequacies in writing.⁴⁹

8 **4. Yeroushalmi Standards Are Met**

9 The Yeroushalmi ruling involved a series of notices sent by a group of plaintiffs relating to
10 second hand tobacco smoke.⁵⁰ On one set, the Court took issue with the fact that the notices in question
11 did not, in even the simplest terms, describe the nature of the violation. On the others, the Court took
12 issue with the fact that the product in question was not identified.

13 The Yeroushalmi decision actually supports Plaintiffs position. There the Plaintiffs had not
14 named any product that caused the exposures in question. They had merely identified the type of
15 exposure, tobacco smoke. This was particularly important in that case since Los Angeles had adopted a
16 city ordinance banning indoor smoking. Since many defendants did not allow smoking in their
17 facilities, they did not know what would be causing the subject exposures. In contrast, in this case, the
18 notice identifies the product type, namely mercury-laden vaccines. Defendants are well aware of how
19 the mercury gets into the vaccines as they place it in them. Further, Defendants are well aware of the
20 subject matter as they have been the subject of Congressional hearings, FDA investigations, and prior to
21 service of the instant 60-day notice, were already defending individual and class cases in several states.
22 This aside, as noted above, any other form of identifying the products in question would either have
23 been inappropriate or violative of the notice regulation.

24 **5. Exposures to Military Personnel Are Expressly not Occupational Exposures** 25 **under Proposition 65**

26 Contrary to Defendants’ contention about military personnel, “[a] ‘consumer products exposure’

27 ⁴⁸See e.g. Letter of January 22, 2002 from Ed Weil to Kamran Ghalchi wherein Mr. Weil asks for
28 further information regarding the case (Exhibit “Q”); see, also, Letter dated September 25, 2002, from
29 Deputy Attorney General Dennis A. Ragen, Esq. to Kamran Ghalchi confirming receipt of evidence and
30 other information which was requested by the AG’s office, including 14 binders of studies, expert reports,
31 various test data, reports by investigators, and copies of various pleadings and correspondence.
32 Significantly, in his letter, Mr. Ragen provides an evaluation of the subject claims.

⁴⁹Khorrami Dec. at ¶5. Plaintiffs are not aware of whether and to what extent Defendants have
been in contact with the AG.

⁵⁰The Yeroushalmi plaintiffs and attorneys, were the primary sources of the “abusive actions by
private persons containing little or no supporting evidence” which led to the passage of SB 471. These
lawyers were notorious for sending improper and inadequate notices in virtually all of their actions.

1 is an exposure which results from a person’s acquisition, purchase, storage, *consumption, or other*
2 *reasonably foreseeable use* of a consumer good, *or any exposure that results from receiving a consumer*
3 *service.*” Emphasis added. Defendants apparently believe that a consumer products exposure can only
4 occur from the “acquisition” of a product. See Defendants’ Demurrer at 24:15. The fundamental flaw in
5 Defendants’ argument is that they assume any exposure to any worker in any work setting constitutes an
6 “occupational” exposure within the meaning of the Act. Contrary to Defendants’ assumption, OSHA’s
7 well defined set of Hazard Communication regulations do not cover all exposures from all toxins in all
8 work places. By its own letter, the federal OSHA regulations do no cover all workers: “[T]his
9 occupational safety and health standard is intended to address the issue of . . . communicating
10 information concerning hazards and appropriate protective measures to employees . . . The term
11 ‘employee’ does not apply to all workers.⁵¹”

12 Vaccines are a consumer product and they relate to the personal health and welfare of an
13 individual. They do not cease to be consumer products simply because they are administered in the
14 military. The fact that administration of vaccines does not constitute an “occupational” exposure is also
15 readily apparent from the fact that it is explicitly exempted from the California Hazard Communications
16 Act, the act which governs occupational exposures.⁵² As such, Plaintiffs need not send notices alleging
17 occupational exposures.⁵³

18 **V. PLAINTIFFS NEED NOT PROVIDE A 60-DAY NOTICE IN ORDER TO PROCEED**
19 **WITH THEIR UCL CAUSE OF ACTION**

20 Defendants ask this Court to dismiss Plaintiffs UCL claim based on Defendants’ assertion that
21 Plaintiffs’ 60-day notices were inadequate. This contradicts an unbroken line of California authority
22 spanning more a quarter of a century. Defendants improperly attempt to argue that alleged lack of
23 standing under Proposition 65 defeats a UCL claim. It is telling that they have not cited to a single case
24 that supports their contention.

25 It is important to distinguish between what constitutes a violation of Proposition 65 on the one
26 hand, and the manner in which a private enforcer can prosecute a Proposition 65 violation on the other.
27 In this case, a violation of Proposition 65 occurred when Defendant caused exposures to mercury
28 through vaccinations. This is the predicate offense which is the subject of the Second Cause of Action.
29 As to Plaintiffs Proposition 65 cause of action, Plaintiffs have to serve a 60-day notice. HSC
30 §25249.7(d). In the second cause of action, Plaintiffs have elected to prosecute violations of the UCL

31 ⁵¹29 CFR 1910.1200, cited in FSR for 12601(c), at 34

32 ⁵²8 CCR 5194(b)(5)(E).

⁵³To the extent that the Court wishes to further entertain this argument, Plaintiffs request a further briefing schedule as Defendants’ Demurrer on this matter did not provide sufficient information as to Defendants’ argument(s) for Plaintiffs to address them in any further detail.

1 that are predicated on Proposition 65. As such, Plaintiffs are not subject to the pre-litigation
2 requirements of HSC §25249.7(d),⁵⁴ because Plaintiffs seek relief from Defendants’ unfair business
3 practices under B&PC 17200 et seq.⁵⁵

4 Moreover, the law in California, generally, and OEHHA’s regulation on 60-Day Notices,
5 specifically, clearly recognize that a 60-Day Notice under the Proposition 65 is *not* a jurisdictional or
6 standing requirement. In its FSR for the notice of violation regulation (22 CCR 12903), OEHHA
7 specifically stated:

8 We note, however, that the agency has avoided using the term “jurisdiction.” That term is
9 commonly used with reference to actions under federal statutes, because federal courts are courts
10 of limited jurisdiction. This term may not be appropriate with respect to California courts, and
11 might implicate other issues concerning the court’s authority to entertain the dispute, which the
12 agency did not wish to address in this regulation.⁵⁶

13 **A. THE UCL CONFERS SEPARATE STANDING UPON A PLAINTIFF AND DOES
14 NOT RELY ON ANY PREDICATE OFFENSE FOR STANDING**

15 When suing under the UCL, a plaintiff need not show that she has been actually injured by the
16 violative practice or even that the predicate law provides for private enforcement.⁵⁷ In fact, Plaintiff
17 need not show standing under the predicate offense at all, only under the UCL.⁵⁸ The UCL allows any
18 person to sue on his or her own behalf, on behalf of their members, or on behalf of the general public.
19 *Id.* Any unlawful, and therefore unfair, practice is properly subject to suit under the UCL. “As our
20 Supreme Court put it, section 17200 ‘borrows’ violations of other laws and treats them as unlawful
21 practices independently actionable under section 17200 et seq.”⁵⁹

22 In Consumers Union, a nonprofit organization brought a UCL action predicated on violations of
23 the Unruh Civil Rights Act (Cal. Civ. Code §51 et seq.), which contains an express standing provision,
24 stating that civil actions for injunctive or other preventive relief may be brought by “the Attorney
25 General, any district attorney or city attorney, or *any person aggrieved . . .*”⁶⁰ The defendant argued that
26 on the standing issue, the “general provisions” of the UCL must give way to the “specific provisions” of
27 the Unruh Act. *Id.* at 1439. Much like Defendants, here, the defendant in that case (Fisher) asserted

28 ⁵⁴This reasoning applies equally to Katrina Bothwell, who did not serve any defendant with a
29 Proposition 65 notice.

30 ⁵⁵Stop Youth Addiction, Inc., v. Lucky Store Inc., (1998) 17 Cal.4th 553, 566 (“[Plaintiff] seeks
31 relief from alleged unfair competition, not to enforce the Penal Code.”).

32 ⁵⁶OEHHA, FSR to Section 12903 at 5 (Exhibit “T” to the Khorrami Dec.)

⁵⁷Saunders v. Superior Court (1994) 27 Cal.App.4th 832, 838-39.

⁵⁸Business & Professions Code § 17204; *see also* Consumers Union of United States, Inc. v. Fisher
Development, Inc. (1989) 208 Cal.App.3d 1433, 1438; People v. McKale (1979) 25 Cal.3d 626; Hewlett
v. Squaw Valley Ski Corp. 54 Cal.App.4th 499.

⁵⁹Olsen v. Breeze, Inc. (1996) 48 Cal.App.4th 608, 618 [citation omitted]

⁶⁰Consumers Union, *supra*, fn 3, *citing* Civil Code §52(c).

1 that any other result would render the standing limitations in the Unruh Act “completely meaningless.”⁶¹
2 The court held that contrary to Fisher’s assertion, parties have been allowed to bring lawsuits under the
3 UCL, “in order to enforce other statutes under which such parties would otherwise *lack standing*.” *Id.*
4 Emphasis added. Citing to B&P section 17205⁶² and the Supreme Court in McKale, *supra*, the Court
5 held that plaintiff need not meet the standing requirements of the Unruh Act because the Unruh Act
6 simply contains an express grant of standing to some persons without any provision restricting or
7 precluding others from proceeding under the UCL.⁶³

8 In McKale, a District Attorney brought a UCL action predicated on violations of the
9 Mobilehome Parks Act (“MPA”). The MPA vested sole authority for bringing enforcement actions in
10 the Commission on Housing and Community Development. Defendants contended that “maintenance
11 of a cause of action in unfair competition for violations of the [MPA] circumvents the specific statutory
12 enforcement scheme provided by the act.”⁶⁴ The Supreme Court unequivocally rejected that contention,
13 holding that while a D.A. may prosecute civil actions only when specifically authorized by the
14 Legislature, lack of express authority to prosecute under the MPA does not preclude an action under the
15 UCL. The High Court further noted that:

[B&P C.] section 17205 also provides that remedies and penalties available in an unfair
competition action are cumulative to remedies and penalties available under other state laws,
unless otherwise expressly provided. Neither the [MPA] nor other statute expressly provides
that violations of the [MPA] may not be prosecuted as acts of unfair competition.⁶⁵

18 McKale which has been cited time and again, thus stands for the proposition that unless the
19 predicate statute expressly provides that violations *may not* be prosecuted under the UCL, a party need
20 only satisfy the broad standing provisions⁶⁶ of the UCL in order to proceed thereunder.⁶⁷

21 In Stop Youth Addiction, *supra*, the California Attorney General filed an amicus brief
22 *contesting* standing where the predicate offense was Penal Code §308. The AG argued that “to confer
23 standing on [plaintiff] would transform the criminal law into a body of civil law giving rise to private
24

25 ⁶¹*Id.* at 1439 and Defendants’ Demurrer at 26:22-25.

26 ⁶²“Unless *otherwise expressly provided*, the remedies or penalties provided by this chapter are
cumulative to each other and to the remedies or penalties available under all other laws of this state.” HSC
27 §17205 (emphasis added).

28 ⁶³Consumers Union, *supra*, at 1441.

29 ⁶⁴People v. McKale, *supra*, at 632; *see also*, Hewlett, *supra*, 54 Cal.App.4th 499 (violation of
conditional use permit, and temporary restraining order, each held to be separately actionable);

30 ⁶⁵*Id.* at p. 633 (internal citation omitted).

31 ⁶⁶Consumers Union, *supra* at 1441 *citing* McKale (“the Supreme Court upheld the standing
provisions of the unfair competition statute in the broadest possible terms . . .”); *see also*, Stop Youth
Addiction, Inc. *supra*, 17 cal.4th at 562 (“Thus, as we have long recognized, it is in enacting the UCL
itself, and not by virtue of particular predicate statutes, that the Legislature has conferred upon private
32 plaintiffs “specific power” to prosecute unfair competition claims.”) (internal citation omitted).

⁶⁷*See, e.g.*, Committee on Children's Television, Inc. v. General Foods Corp., (1983) 35 Cal.3d 197;
Hewlett, *supra*.

1 causes of action.” The Court reasoned that this was a mischaracterization of plaintiff’s position – that
2 the plaintiff did not assert that it had a private right of action, nor was it attempting to enforce the Penal
3 Code, Plaintiff was merely seeking relief from unfair competition.

4 In the present case, even if Plaintiffs were barred from maintaining a Proposition 65 action due
5 to alleged defects in their 60-day notice,⁶⁸ they may proceed under the UCL because the UCL has no 60-
6 day notice requirement. A violation of Proposition 65 would still provide a viable basis for a private
7 cause of action under the UCL even if Proposition 65 did not have a citizen enforcement provision at
8 all. Therefore, despite any 60-day-notice requirements under Proposition 65, Defendants’ demurrer as
9 to the UCL claim predicated on Proposition 65 must be denied. As the Stop Youth Addiction court
10 declared, Plaintiffs are not attempting to enforce Proposition 65 in their second cause of action, but
11 merely seeking relief for unfair competition.

12 Aside from the fact that Defendants have not cited to a single published decision that supports
13 their reasoning, their attempt at distinguishing Stop Youth Addition, the only case to which they cite, is
14 utterly meritless. Basically, Defendants argue that since there is a possibility of bringing a private
15 action under Proposition 65, this Court should force a plaintiff to send out a 60-day notice. However, if
16 as in Stop Youth Addiction, a private suit was completely precluded under the predicate statute, the
17 Court is correct in completely ignoring such a preclusion. This is exactly what the McKale Court
18 rejected a quarter of a century ago. In that case, it was possible to bring a private suit, but, one needed
19 to be aggrieved. The Court soundly rejected defendant’s “standing” argument. Equally spurious is
20 Defendants’ argument that somehow the integrity of Proposition 65 can be damaged if Plaintiffs were
21 not forced to send out 60-day notices for UCL actions. As noted below, the UCL provides for different
22 remedies, including the fact that a plaintiff who proceeds under UCL may not make a penalties claim.

23 **B. DEFENDANTS’ CONTENTION REGARDING THE NOTICE REQUIREMENT**
24 **IS FUNDAMENTALLY FLAWED AND VIOLATES THE BASIC PRINCIPLES**
25 **OF THE UCL.**

26 The UCL is focused entirely on a defendant’s conduct. If the defendant engages in a business
27 practice that is unfair, unlawful, or deceptive, it is subject to suit under the UCL. “The Legislature
28 apparently intended to permit courts to enjoin ongoing wrongful business conduct in whatever context
29 such activity might occur.”⁶⁹ This works hand-in-hand with the UCL’s broad standing provision. In the
30 instant case, as soon as Defendants caused an exposure as defined under the Act, they engaged in an
31 unlawful business practice which was actionable under the UCL. No pre-litigation steps are required

31 ⁶⁸And even if, like Katrina Bothwell, they had not sent a 60-day notice at all.

32 ⁶⁹Hewlett, supra, 54 Cal.App.4th at 519; *see also*, Committee on Children's Television, supra, 35
Cal.3d at 210; *accord*, Farmers Ins. Exchange v. Superior Court (1992) 2 Cal.4th 377, 383; Consumers
Union, supra, 208 Cal.App.3d at 1438-1439.

1 before any private plaintiff may bring an action to prosecute this violation because Defendants’ business
2 practices do not become unlawful upon the satisfaction of the notice requirements.

3 Another point to consider is that the UCL’s statute of limitations is four years, whereas
4 Proposition 65’s is only one year. Even the best 60-day notice necessarily would not cover violations
5 beyond Proposition 65’s statute of limitations. Thus, Plaintiffs, through their UCL claim, would seek
6 relief for some 3 years of “un-noticed” unfair practices. Yet Defendants seem to have no trouble with
7 that concept at all. They apparently would be satisfied with having to answer for 4 years of violations
8 so long as they have a 60-day notice covering one. The reason is simple: There is no need to serve a 60-
9 day notice for a UCL claim predicated on Proposition 65.

10 **C. REQUIRING PRIVATE PLAINTIFFS TO SERVE 60 DAY NOTICES PRIOR TO**
11 **BRINGING §17200 CLAIMS WOULD UNDULY LIMIT THE BROAD**
STANDING PROVISIONS OF THE UCL.

12 The California Supreme Court has held that the standing provisions of the UCL must be read in
13 the broadest possible terms, finding standing unless otherwise expressly provided.⁷⁰ Defendants can
14 cite to no authority for their position that Plaintiffs must meet the 60-day notice requirement in order to
15 maintain a UCL claim. In fact, requiring private plaintiffs to serve 60-day notices before bringing a
16 UCL claim would be unprecedented and against the express mandate of an unbroken line of case law.
17 Nothing cited by Defendants provides a basis for reading pre-filing requirements of Proposition 65 into
18 the UCL. Contrary to Defendants’ assertion, and as noted above, courts have repeatedly permitted
19 plaintiffs to bring suit under the unfair competition statutes on behalf of the general public in order to
20 enforce other statutes under which such parties would otherwise lack standing.⁷¹

21 **D. ALLOWING PLAINTIFFS TO GO FORWARD WITH THEIR UCL CLAIM IS**
22 **CONSISTENT WITH THE SPIRIT OF THE UCL AND PROMOTES THE**
PUBLIC POLICY OF SUPPORTING ITS BROAD STANDING PROVISIONS.

23 The language of the UCL has consistently been interpreted broadly.⁷² Our Supreme Court has
24 repeatedly given the broadest possible definition to the term “unfair competition.”⁷³ In fact, in
25 Committee on Children’s Television, the Supreme Court, citing to some 30 years of case law and
26 literature, explained the legislative intent for liberal application of its broad standing provision:

27 “[T]he language of section 17200 demonstrates a clear design to protect consumers . . .
28 permitting inter alia, *any member of the public* to sue on his [or her] own behalf or *on behalf of*
the public generally.’ [Citation.] . . . The Legislature apparently intended to permit courts to

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31 ⁷⁰Consumers Union, *supra*, at 1441, *citing McKale*.

32 ⁷¹Consumers Union, *supra*.

⁷²People v. McKale, *supra*, 25 Cal.3d at pp. 631-632 *citing Barquis v. Merchants Collection Assn.*
(1972) 7 Cal.3d 94; *see also Consumers Union*, *supra*, at 1439.

⁷³Consumers Union, *supra*, at 1438-1439.

1 enjoin ongoing wrongful business conduct *in whatever context such activity might occur.*”⁷⁴

2 Defendants’ demurrer to Plaintiffs’ UCL Cause of Action is an invitation for this Court not only
3 to ignore the repeated mandates of our Supreme Court, but also to violate the legislature’s intent by
4 taking the unprecedented step of reading into the UCL, a 60-day notice requirement where Proposition
5 65 is the predicate offense.

6 **E. DEFENDANTS’ PREDICTIONS OF DOOM FOR PROPOSITION 65**
7 **PROCEDURE AND ENFORCEMENT ARE BASELESS**

8 **1. The 60-Day Notice Provisions of Proposition 65 Remain Unaffected.**

9 Defendants imply that allowing a UCL claim without a 60-day notice would somehow cause
10 private plaintiffs to no longer bring Proposition 65 causes of action for the sole purpose of getting
11 around the notice requirement. This argument is meritless on its face. To begin with, by bringing a
12 UCL case, Plaintiffs are precluded from obtaining any penalties. Furthermore, contrary to Defendants’
13 assertion, even if plaintiffs intended to deprive public prosecutors of an opportunity to prosecute the
14 case, bringing only a UCL claim does not even go toward accomplishing such an objective. In fact, it
15 not only leaves public prosecutors’ authority untouched, but it would not even preclude a different
16 private enforcer from sending out 60-day notices and commencing a Proposition 65 action.

17 Defendants’ further argument that the Court is creating an exemption to the notice requirement
18 completely misses the point as well. If Defendants are speaking to the UCL, since the UCL does not
19 contain a notice requirement, the Court will not be creating an exemption by holding that Plaintiffs need
20 not send a notice. If Defendants are speaking to Proposition 65, by holding that there is no 60-day
21 notice requirement in a UCL claim, the Court is saying nothing about Proposition 65. Any plaintiff that
22 wishes to bring a Proposition 65 case, still must serve 60-day notices on Defendants and public
23 prosecutors. No exemption is created.

24 **2. Public Prosecutors’ Power to Bring the Proposition 65 Case Is Unaffected.**

25 Plaintiffs’ Second Cause of Action is not a Proposition 65 claim. Public prosecutors can bring a
26 Proposition 65 case if they so wish. They have not been deprived of that opportunity in any way. In
27 fact, although Plaintiffs are not hereby conceding, the Attorney General has in the past asserted that he
28 can step into a Proposition 65 case even after a private plaintiff has initiated suit. Whether or not
29 Plaintiffs serve 60-day notices does not deprive the Attorney General of any opportunities he may have

30 ⁷⁴Committee on Children's Television, Inc., supra, 35 Cal.3d at p. 210 *citing Barquis, supra*, 7
31 Cal.3d 94 (emphasis added); People v. McKale, supra, at 632; *see also* Howard, Former Civil Code,
32 Section 3369: A Study in Judicial Interpretation (1979) 30 Hastings L.J. 705; *Note, Unlawful Agricultural*
Working Conditions as Nuisance or Unfair Competition (1968) 19 Hastings L.J. 398, 408-409); *see also*
Stoiber v. Honeychuck (1980) 101 Cal.App.3d 903, 927; *accord, Farmers Ins. Exchange v. Superior Court*
(1992) 2 Cal.4th 377, 383; Consumers Union, supra, 208 Cal.App.3d at 1438-1439.

1 under Proposition 65. The crucial issue is that under the UCL, Plaintiffs need not send notices to
2 defendants or to the public prosecutors.

3 **VI. CONCLUSION**

4 For the foregoing reasons, Defendants' Demurrer should be denied.

5 Dated: April 15, 2003

LAW OFFICES OF SHAWN KHORRAMI

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By: _____
SHAWN KHORRAMI, ESQ.
Attorneys for Plaintiffs

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1 **PROOF OF SERVICE BY EMAIL**

2 STATE OF CALIFORNIA, COUNTY OF LOS ANGELES

3 I am employed in the County of Los Angeles, State of California. I am over the age of 18 and
4 not a party to this action. My business address is 14550 Haynes Street, 3rd Floor Van Nuys, CA. 91411

5 On April 15, 2003, I served the foregoing:

6 **PLAINTIFFS' OPPOSITION TO DEFENDANTS' DEMURRER TO MASTER COMPLAINT
NO. 3**

7 By email transmission to the individual(s) and email address(es) set forth below. I caused the above-
8 mentioned document(s) to be transmitted by email to the address(es) listed below at the email
9 address(es) listed below. I am readily familiar with this office's practice for transmissions by email.
10 Transmissions are sent as soon as possible and are repeated, if necessary, until they are reported as
11 complete and without error. In sending the foregoing document(s) by email, I followed this office's
12 ordinary business practices. The sending email address is kgilbert@khorrami.com.

13 [See Attached Service List]

14 Executed on April 15, 2003 at Van Nuys, California.

15 _____
16 KAIA GILBERT
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