

SUPERIOR COURT OF CALIFORNIA, COUNTY OF LOS ANGELES

DATE: 05/16/03

DEPT. .24

HONORABLE VICTORIA CHANEY

JUDGE

E. SABALBURO

DEPUTY CLERK

HONORABLE
#1

JUDGE PRO TEM

ELECTRONIC RECORDING MONITOR

F. LOPEZ, CRT. ASST.

Deputy Sheriff

NONE

Reporter

9:00 am

JCCP4246

Plaintiff

Counsel

Coordination Proceeding Special
Title (Rule 1550 (b))

Defendant

Counsel

The Vaccine Cases

NO APPEARANCES

NATURE OF PROCEEDINGS:

RULING ON SUBMITTED MATTERS HEARD MAY 12, 2003

The court hereby makes its ruling pursuant to its "RULING ON DEFENDANTS' DEMURRER TO MASTER COMPLAINT NO. 3 AND MOTION TO STRIKE PORTIONS OF MASTER COMPLAINT NO. 3" as signed and filed this date.

Defendants' Demurrer to the first and second causes of action is SUSTAINED without leave to amend. The Motion to Strike Portions of Master Complaint No. 3 is moot.

Counsel Fletcher C. Alford is ordered to serve a copy of this minute order and the court's ruling to all parties within ten days.

CLERK'S CERTIFICATE OF MAILING/
NOTICE OF ENTRY OF ORDER

I, the below named Executive Officer/Clerk of the above-entitled court, do hereby certify that I am not a party to the cause herein, and that this date I served Notice of Entry of the above minute order of 5-16-2003 upon each party or counsel named below by depositing in the United States mail at the courthouse in Los Angeles, California, one copy of the original entered herein in a separate sealed envelope for each, addressed as shown below with the postage thereon fully prepaid.

<p align="center">MINUTES ENTERED 05/16/03 COUNTY CLERK</p>

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NATURE OF PROCEEDINGS:

Date: 5-16-2003

John A. Clarke, Executive Officer/Clerk

By: 

E. Sabalbuoro

Fletcher C. Alford
GORDON & REES
Embarcadero Center, West
275 Battery Street, Suite 2000
San Francisco, CA 94111

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SUPERIOR COURT OF CALIFORNIA
COUNTY OF LOS ANGELES

ORIGINAL FILED
MAY 16 2003
LOS ANGELES
SUPERIOR COURT

THE VACCINE CASES

CASE NO. JCCP 4246

RULING ON DEFENDANTS'
DEMURRER TO MASTER COMPLAINT
NO. 3 AND MOTION TO STRIKE
PORTIONS OF MASTER COMPLAINT
NO. 3

Hearing date: 5/12/03

Ruling date: 5/16/03

After considering the moving, opposing, and reply papers and the arguments of counsel at the hearing, the court now rules as follows:

Defendants' Demurrer to the first and second causes of action is SUSTAINED without leave to amend.

Defendant Wyeth on its own behalf and on behalf of Defendants Abbot laboratories, Aventis Pasteur, Inc., individually and as successor to Connaught Laboratories, Inc., Pasteur Merieux, and Pasteur Merieux Connaught; Bergen Brunswick Corporation; Eli Lilly and Company; King Pharmaceuticals, Inc. dba Parkdale Pharmaceuticals, Inc.; Merck & Co., Inc.; Priority Healthcare Corp.; Sigma-Aldrich Corp.; SmithKline Beecham Corporation dba GlaxoSmithKline; and Spectrum Laboratory Product, Inc. (Defendants) demur to plaintiffs' Master Complaint No. 3 on the following grounds:

- 1 1. The court lacks subject matter jurisdiction;
- 2 2. Plaintiffs do not have the legal capacity to sue;
- 3 3. The first and second causes of action fail to state a valid claim;
- 4 4. The first and second causes of action are uncertain, in that they fail
- 5 to clearly identify the products that are at issue; fail to clearly identify the
- 6 alleged defendants, their status, and their relationship to the products in
- 7 question; and fail to clearly identify the persons who were allegedly
- 8 exposed to those products.

9
10 Joinders in support of the motion have been filed by Defendants
11 SmithKline Beecham, Priority Healthcare Corp., Celltech Pharmaceuticlas, Inc., and Eli
12 Lilli and Company.

13 Plaintiff's Master Complaint No. 3 alleges that Defendants violated Proposition 65
14 (Prop. 65) by exposing consumers to vaccines containing thimerosal without providing a
15 "clear and reasonable warning" as required by Health and Safety Code section 25249.6.

16
17 **I. California Code of Regulations, Title 22, Section 12601(b)(2)**

18 **A. Section 12601(b)(2)**

19
20 The California Health and Welfare Agency (CHWA), the agency initially
21 designated to administer Prop. 65, adopted an implementing regulation stating:

22 For prescription drugs, the labeling approved or otherwise provided under
23 federal law and the prescriber's accepted practice of obtaining a patient's
24 informed consent shall be deemed a clear and reasonable warning.

25 (Cal. Code Regs, tit. 22, § 12601(b)(2).)

26 The plain language of the regulation provides a safe harbor for prescription drugs
27 carrying an FDA-approved label from the warning requirements of Prop. 65. This court
28 will not read into the regulation, as Plaintiff urges, a qualification that section

1 12601(b)(2) only applies where the FDA-approved label specifically warns of cancer or
2 reproductive harm. (See CHWA Final Statement of Reasons, pp. 7, 22-23.)

3 Plaintiffs also argue that CHWA exceeded its authority in adopting section
4 12601(b)(2). “In reviewing the legality of a regulation adopted pursuant to a delegation of
5 legislative power, the judicial function is limited to determining whether the regulation
6 (1) is within the scope of the authority conferred and (2) is reasonably necessary to
7 effectuate the purpose of the statute.” (*Ramirez v. Yosemite Water Co., Inc.* (1999) 20
8 Cal.4th 785, 800.)

9 The power delegated to CHWA is to “implement the provisions of [Proposition
10 65] ... [and to] adopt and modify regulations, standards, and permits as necessary to
11 conform with and implement the provisions of this chapter and to further its purposes.”
12 (Health & Saf. Code, § 25249.12.) CHWA’s stated purpose in adopting section
13 12601(b)(2) is to provide standards for the implementation of Proposition 65’s “clear and
14 reasonable warning” requirement. (CHWA Final Statement of Reasons, p. 1.) Therefore,
15 the adoption of section 12601(b)(2) is within the scope of the power delegated to the
16 agency.

17 The second prong in a determination of the legality of a regulation is whether the
18 regulation “is reasonably necessary to effectuate the purposes of the statute.” (*Ramirez v.*
19 *Yosemite Water Co., Inc., supra*, 20 Cal.4th at p. 800.) The purpose of Proposition 65 is
20 to effectuate the right of the People of the State of California “t[o] be informed about
21 exposures to chemicals that cause cancer, birth defects and reproductive harm.” (Text of
22 Prop. 65, § 1(b), reprinted in Historical and Statutory Notes, 40C West’s Ann. Health &
23 Saf. Code (1999 ed.) foll. § 25249.5, pp. 279-280.) In its Final Statement of Reasons, the
24 CHWA considered objections to section 12601(b)(2) on the ground that it offered no
25 assurance that any warning would be received from physicians. The agency responded
26 that “the informed consent standard seems to be appropriate, since one purpose of the
27 doctrine is to impose liability where the patient has not been adequately informed.... This
28 is similar to one purpose of the Act, which is to enable individuals to make informed
choices about being exposed to listed chemicals.” (Revised Final Statement of Reasons,

1 p. 22.) Thus, the agency was convinced that the regulation would carry out the purpose
2 of Proposition 65.

3 Courts “accord great weight and respect to” an agency’s interpretation of its own
4 regulations and are “more likely to defer to an agency’s interpretation of its own
5 regulation than to its interpretation of a statute, since the agency is likely to be intimately
6 familiar with regulations it authored and sensitive the practical implications of one
7 interpretation over another.” (*Yamaha Corp. of America v. State Bd. of Equalization*
8 (1998) 19 Cal.4th 1, 12.) Therefore, this court will defer to CHWA’s interpretation of the
9 regulation as being reasonably necessary to further the purposes of Proposition 65.

10 Because Defendants’ products fall within the safe harbor of section 12601(b)(2),
11 Plaintiffs cannot state a claim for violation of Health and Safety Code section 25249.6 et
12 seq.

13 14 **B. Collateral Estoppel**

15
16 Defendants also argue that Plaintiffs’ claims are precluded by a San Diego
17 Superior Court case, *California v. Alpharma USPD, Inc.*, Case No 992915. Whether this
18 is so remains for another day. The question of whether that judgment has preclusive
19 effect involves an impermissible factual inquiry not proper on demurrer.

20 21 **II. Federal Preemption**

22
23 Ordinarily, state common-law failure to warn claims for damages are not
24 preempted by Prop. 65. (*Motus v. Pfizer Inc.* (C.D.Cal. 2000) 127 F.Supp.2d 1085,
25 1092.) However, in this case, plaintiffs seek an injunction compelling defendants to
26 change their federally mandated labeling. (Master Complaint No. 3, p. 17, lines 2-15.)
27 This creates a conflict between the FDA mandate that Defendants use the exact labeling
28 approved by the federal agency and the injunction sought by Plaintiffs to change that
labeling.

1 Vaccines are subject to the Federal Food, Drug, and Cosmetic Act. (21 U.S.C. §
2 321(g)(1).) The FDA reviews and approves the information prescription drug
3 manufacturers include in package inserts, the primary form of labeling for prescription
4 drugs. (21 C.F.R. §§ 201.56, 201.57, 201.100(d).) Any safety-related information must
5 be included in any advertising for prescription drugs. (21 U.S.C. § 352(n).) Once
6 approved, the label may not be changed without FDA approval. (See *Ehlis v. Shire*
7 *Richwood, Inc.* (D.N.D. 2002) 233 F.Supp.2d 1189, 1198.)

8 An injunction requiring Defendants to change the FDA-mandated labeling would
9 make it impossible for Defendants to comply with both the federal regulatory scheme and
10 the state court injunction. Therefore, such an injunction would be preempted. (See
11 *People ex rel. Lungren v. Cotter & Co.* (1997) 53 Cal.App.4th 1373, 1393-1394.)
12 Plaintiffs assert that preemption may be avoided by providing notice through placards or
13 signs posted in doctors' offices, or through doctors themselves. However, the FDA
14 governs *all* product information materials relating to prescription drugs, including
15 advertising, brochures and postings, whether physically attached to the product or not.
16 (21 C.F.R. § 202.1(l)(1) & (2).) Because Plaintiffs' claims conflict with federal
17 regulation of vaccines, those claims are preempted.

18 19 **III. Plaintiffs' 60-Day Notice**

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21 The general rule is that "statutes do not operate retrospectively unless the
22 Legislature plainly intended them to do so." (*Western Sec. Bank v. Superior Court*
23 (1997) 15 Cal.4th 232, 243.) Nothing in SB 471 states that it applies retroactively.
24 Therefore, Plaintiffs' 60-day notices did not require a certificate of merit.

25 26 **IV. Plaintiffs' UCL claim**

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28 Plaintiffs' UCL cause of action is solely predicated upon Defendants' alleged
violations of Prop. 65. (Master Complaint No. 3, ¶¶ 65-79.) Because Plaintiffs cannot

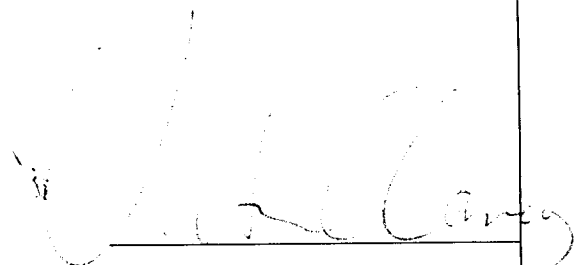
1 state a claim for violation of Prop. 65, plaintiffs' UCL claim also fails, and the demurrer
2 is sustained without leave to amend as to the second cause of action as well.

3
4 **In sum:**

5 **Defendants' Demurrer to the first and second causes of action is**
6 **SUSTAINED without leave to amend. The Motion to Strike Portions of Master**
7 **Complaint No. 3 is moot.**

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10 IT IS SO ORDERED.

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12 Dated: 5/16/03



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14 Victoria Gerrard Chaney

15 Judge
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