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Submitted on Behalf of the Plaintiffs' Executive Committee
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13 COORDINATION PROCEEDING)
SPECIAL TITLE: IN re DIET DRUGS (FEN-)
14 PHEN))
_____)
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Judicial Council Coordination
Proceeding No. 4032

**PLAINTIFFS' MEMORANDUM OF
POINTS AND AUTHORITIES IN
SUPPORT OF MOTION TO AMEND
COMPLAINT**

Date: January 22, 1999
Time: 9:00 a.m.
Dept: SE-D
Hon. Daniel S. Pratt
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I.

INTRODUCTION

Plaintiffs seek to amend the Master Complaint in this case in the following manner:

1. Add causes of action for strict liability (failure to warn), negligence and negligence *per se* based upon a market share theory of liability against the phentermine defendants.
2. Add pharmacies as defendants and add causes of action for negligence, negligence *per se*, Violation of Business & Professions Code § 17200 and Violation of Business & Professions Code § 17500.
3. Add the Servier entities as defendants and add the same causes of action against them as are alleged against the pharmaceutical defendants.
4. Correct the name of defendant Eon Labs Manufacturing, Inc. which was named as Eon Laboratories Manufacturing, Inc. in the Master Complaint and add the following phentermine manufacturer: Rhone-Poulenc Rorer, Inc.

II.

FACTUAL BACKGROUND

These coordinated actions all involve the diet drugs which are commonly known as “fen-phen.” Fen-phen is actually two different drugs, fenfluramine and phentermine which were taken together by plaintiffs in an effort to lose weight. Defendants misrepresented that fen-phen was a safe and effective way to lose weight, when in fact the drugs cause serious medical problems such as primary pulmonary hypertension and valvular heart disease.

Pondimin and Redux are the trade names of the generic drugs fenfluramine and dexfenfluramine. Defendants American Home Products, Wyeth-Ayerst Laboratories, A.H. Robins Company, Inc. and Interneuron each participate in the manufacture, marketing, distribution and sale of fenfluramine and/or dexfenfluramine. The Servier entities that plaintiffs seek to add as defendants, Les Laboratoires Servier, Science Union et Cie, Oril, Orsem, Servier Amerique, Institue de

1 Recherches Internationales Servier, are French companies who licensed, manufactured and sold
2 fenfluramine and dexfenfluramine to the other defendants. Plaintiffs seek to add the Servier entities as
3 defendants in this action as their conduct and participation in the manufacturing, marketing,
4 distribution and sale of fenfluramine and dexfenfluramine gives rise to liability.

5 Plaintiffs also seek to amend the complaint to allege a market share theory of liability against
6 the phentermine defendants. There are many manufacturers of phentermine, a fungible drug.
7 Plaintiffs have sued the phentermine defendants who comprise a substantial portion of the market.
8 Although plaintiffs have attempted to identify the manufacturers, in many instances plaintiffs, through
9 no fault of their own, are not able to identify the phentermine manufacturer. Therefore, plaintiffs seek
10 to allege a market share theory of liability. Plaintiffs also seek to add an additional phentermine
11 manufacturer and correct the name of one phentermine manufacturer.

12 Additionally, plaintiffs seek to add to the Master Complaint causes of actions against
13 pharmacies. The pharmacies have breached their duties to plaintiffs.

14 III.

15 LEGAL ARGUMENT

16 A. THE COURT SHOULD ALLOW PLAINTIFFS 17 TO AMEND THE MASTER COMPLAINT

18 The Court should allow plaintiffs to amend the Master Complaint. Code of Civil Procedure §
19 473(a)(1) provides that:

20 The court may, in furtherance of justice, and on any terms as may be proper, allow a
21 party to amend any pleading or proceeding by adding or striking out the name of any
22 party, or by correcting a mistake in the in the name of a party, or a mistake in any
23 other respect; and may, upon like terms, enlarge the time for answer or demurrer. The
24 court, may likewise, in its discretion, after notice to the adverse party, allow upon any
25 terms as may be just, an amendment to any pleadings or proceeding in other
26 particulars; and may upon like terms allow an answer to be made after the time limited
by this code.

24 *See also* Code of Civil Procedure § 576 (“Any judge, at any time before or after commencement of
25 trial, in the furtherance of justice, and upon such terms as may be proper, may allow the amendment
26 of any pleading . . .”).

1 Public policy favors the amendment of complaints. “If the motion to amend is timely made
2 and the granting of the motion will not prejudice the opposing party, it is error to refuse permission to
3 amend; and where the refusal also results in a party being deprived of the right to assert a meritorious
4 cause of action or a meritorious defense, it is not only error but an abuse of discretion.” *Morgan v.*
5 *Superior Court* (1959) 172 Cal.App.2d 527, 530; *see Mabie v. Hyatt* (1998) 61 Cal.App.4th 581,
6 596.

7 In this case, it is in the furtherance of justice for the Court to allow plaintiffs to amend the
8 Master Complaint, there will be no prejudice to defendants and it will be a more efficient use of
9 judicial resources to have the Master Complaint amended than to have individual plaintiffs allege
10 these causes of action as add-on causes of action to the Master Complaint.

11 **A. THE COURT SHOULD ALLOW PLAINTIFFS TO AMEND TO ALLEGE FAILURE**
12 **TO WARN AND NEGLIGENCE ON A MARKET SHARE THEORY**

13 Established case law allows plaintiffs to sue manufacturers of a harmful product under a
14 market share theory of liability when the following conditions are met:

- 15 1. The product is fungible;
- 16 2. The product cannot be traced to a specific manufacturer through no fault of plaintiff;
17 and
- 18 3. Plaintiff joins a substantial share of the manufacturers in the litigation.

19 In *Richie v. Bridgestone/Firestone, Inc.* (1994) 22 Cal.App.4th 335, 338, the Court of Appeal
20 described the market share theory of liability as follows:

21 Under the market theory of liability, a plaintiff harmed by a fungible product that
22 cannot be traced to a specific product may sue various makers of the product if the
23 plaintiff joins a substantial share of these makers as defendants.

24 The theory was first developed in *Sindell v. Abbott Laboratories* (1980) 26 Cal.3d 588. In
25 *Sindell*, the plaintiff alleged injury from her mother’s taking of diethylstilbesterol (DES), a miscarriage
26 preventative. As with many of the cases involving DES, plaintiff was unable to identify the particular
manufacturer of the DES her mother took. Plaintiff named 11 of 200 manufacturers of DES. The

1 court noted that DES was produced from an identical formula, and was marketed under many
2 different trade names. The question before the Supreme Court in *Sindell*, just as it is before this
3 Court, was:

4 [M]ay a plaintiff, . . . , who knows the type of drug involved but cannot identify the
5 manufacturer of the precise product, hold liable for her injuries a maker of a drug
produced from an identical formula?

6 *Sindell*, 26 Cal.3d at 593. The Supreme Court answered the question “yes” and created liability in
7 proportion to the manufacturer’s market share. The burden of proof is shifted to the defendant
8 manufacturers to absolve themselves of responsibility. The Supreme Court reasoned that as between
9 an innocent plaintiff and several negligent manufacturers, the manufacturers should bear the cost of
10 injury. *Id.* at 610-611. This is particularly true “where medication is involved, for the consumer is
11 virtually helpless to protect himself from serious, somewhat permanent, sometimes fatal, injuries,
12 caused by deleterious drugs.” *Id.* at 611.

13 This case is on all fours with *Sindell* and is distinguishable from those cases where the courts
14 refused to impose market share liability. Each of the *Sindell* factors is alleged in the proposed First
15 Amended Master Complaint.

16 **1. Fungibility**

17 Like the drug DES in *Sindell*, phentermine is clearly fungible. A product is fungible if it is
18 produced from an identical formula or it is a good so highly similar in composition and use as to be
19 functionally indistinguishable. *See generally Sindell*, 26 Cal.3d at 588; *Wheeler v. Raybestos-*
20 *Manhattan* (1992) 8 Cal.App.4th at 1152. As in *Sindell*, phentermine is produced from an identical
21 formula. The conduct of physicians, weight loss centers and diet centers of switching from one brand
22 of phentermine to another, seemingly from prescription to prescription, is a clear indication of the
23 identical and interchangeable nature of phentermine. Borrowing the court’s language in *Sanderson v.*
24 *International Flavors and Fragrances, Inc.* (C.D. Cal. 1996) 950 F.Supp. 981, 991, when it
25 discussed the fungibility of DES in the *Sindell* decision, the only difference between

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1 phentermine manufactured by SmithKline Beecham and Zenith Goldline Laboratories is the return
2 address on the package sent by the manufacturer to the pharmacy.

3 The fungibility requirement has historically been the one area where courts have been most apt
4 to refuse to apply the market share theory of liability. Unlike this case where phentermine is
5 produced from the same formula and is used interchangeably by prescribers of the drug, courts have
6 refused to apply *Sindell* in cases where the product was not fungible, such as latex gloves (*Kennedy v.*
7 *Baxter* (1996) 43 Cal.App.4th 799-- plaintiff did not allege that the gloves were fungible and made
8 according to the same formula, nor asserted that the gloves contained the same level of the allegedly
9 harmful protein), residential pipes (*Edwards v. A.L. Lease & Company* (1996) 46 Cal.App.4th 1029--
10 not fungible because the pipes contained manufacturing defects rather than design defects as in
11 *Sindell*), perfume (*Sanderson v. International Flavors and Fragrances, Inc.* (C.D. Cal. 1996) 950
12 F.Supp. 981-- perfumes had different compositions and different health effects) and asbestos products
13 (*Rutherford v. Owens-Illinois, Inc.* (1997) 16 Cal.4th 953; *Lineaweaver v. Plant Insulation Co.*
14 (1995) 31 Cal.App.4th 1409; *Mullen v. Armstrong World Industries, Inc.* (1988) 200 Cal.App.3d
15 250; *Setliff v. E.I. Dupont De Nemours & Co.* (1995) 32 Cal.App.4th 1525--asbestos products share
16 the characteristics that they contain asbestos fibers, but they differ in the type of fiber, the percentage
17 of asbestos used in the product and the physical properties of the product itself).

18 Courts have, however, allowed plaintiffs to proceed on a market share theory for brakepads
19 containing roughly the same percentage of asbestos. *Wheeler v. Raybestos-Manhattan* (1992) 8
20 Cal.App.4th 1152. In *Wheeler*, the market share theory was allowed even though brake pads were
21 different shapes and sizes to fit different cars and were not interchangeable from the standpoint of an
22 auto mechanic since they were all composed solely of a specific asbestos fiber and contained roughly
23 the same percentage of asbestos. The *Wheeler* plaintiffs' exposure occurred when the pads were
24 inspected or replaced and the asbestos laden dust was blown out of the brake drums. Here,
25 phentermine is certainly far more fungible than the brake pads in *Wheeler*.

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1 **2. The Product Cannot Be Traced to a Specific Manufacturer**

2 Plaintiffs in this litigation also clearly fulfill the second requirement for imposing market share
3 liability insofar as the theory will be used only in those cases where plaintiffs are unable to identify the
4 phentermine manufacturer after an exhaustive search. As stated in Plaintiffs’ Opposition to Notice of
5 Petition for General Order re Identification/Dismissal of Phentermine Defendants, this search includes
6 plaintiffs’ recollection and description, medical records, exemplars of drugs and/or drug containers,
7 manufacturing and distribution information from defendants, and specific product identification
8 discovery.¹ Only if investigation fails to produce a specific phentermine manufacturer for the
9 particular plaintiff will market share liability be utilized.

10 In *Sindell*, the plaintiff was unable to discover the manufacturer of the drug her mother’s
11 ingested since many years had passed between the time the drug was taken and manifestation of her
12 injury. *Sindell*, 26 Cal.3d at 600-601. In *Wheeler*, the plaintiff could not identify the manufacturer
13 because the exposure to asbestos came from used brake pads where the markings had been worn off
14 from use. *Wheeler*, 8 Cal.App.4th at 1157. In this case, there can be no question that after a full
15 inquiry, which includes information generated by both plaintiffs and defendants, any plaintiff who
16 cannot identify their phentermine manufacturer meets the second *Sindell* requirement.

17 **3. Plaintiffs Join a Substantial Share of the Market**

18 Plaintiffs meet the third *Sindell* requirement by naming as defendants phentermine
19 manufacturers who comprise a substantial share of the market. Under *Sindell*, plaintiffs are obligated
20 to join in the action manufacturers of a substantial share of the phentermine the plaintiff might have
21 ingested. The Supreme Court reasoned that by naming a substantial share of the manufacturers “the

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23 ¹ Plaintiffs’ counsel ran into the same problem in the DES cases. There, the parties’ counsel
24 traveled extensively reviewing drugstore records attempting to identify manufacturers of particular brands
25 of DES. In some of the DES cases, the product identification could be narrowed to a group of 3 or 4
26 manufacturers, but the actual unitary identification was never made. This led to the *Sindell* market share
liability decision. See Declaration of Mark Robinson, Jr. submitted in support of Plaintiffs’ Opposition
to Petition for General Order re Identification/Dismissal of Phentermine Defendants of which the Court
is requested to take judicial notice.

1 injustice of shifting the burden of proof to demonstrate that they could not have made the substance
2 which injured plaintiff is significantly diminished.” *Sindell*, 26 Cal.3d at 612. Under this approach,
3 each manufacturers’ liability approximates the likelihood that they manufactured the drug used.

4 The Supreme Court in *Sindell* did not specify a particular percentage that would constitute a
5 “substantial share” of the market.² The court in *Murphy v. E.R. Squibb & Sons, Inc.* (1985) 40
6 Cal.3d 672 found that 10% of the market was inadequate. In this case, the Amended Master
7 Complaint alleges that the phentermine manufacturers constitute a substantial share of the market.

8 Thus, the Court should allow plaintiffs to amend the Master Complaint to allege market share
9 liability in the negligence, negligence *per se* and strict liability (failure to warn) causes of action. The
10 Adoption Form can be modified accordingly so that plaintiffs can indicate if they are proceeding on a
11 market share liability theory.

12 **C. PLAINTIFFS SHOULD BE PERMITTED TO ALLEGE CAUSES OF ACTION**
13 **AGAINST PHARMACIES IN THE MASTER COMPLAINT**

14 A pharmacist owes a particular duties to its customers.

15 A pharmacist is required not only to assure that the drug prescribed is properly
16 selected, measured and labeled, but according to the Board [of Pharmacy], he must be
17 alert to errors in prescriptions written by doctors, and contact the doctor in case of
18 doubts or questions regarding the drugs prescribed. In addition, the pharmacist may
19 discuss with the patient the proper use of the drug and the potential side effects and
20 must be aware of the possibility of harmful interaction between various medications
21 with the pharmacist knows the patient is using.

18 *Murphy v. E.R. Squibb & Sons, Inc.* (1985) 40 Cal.3d 672, 678; *see also Huggins. v. Longs Drug*
19 *Stores California, Inc.* (1993) 6 Cal.4th 124, 132. (Citations omitted).

20 Pursuant to California regulations:

21 (a) A pharmacist shall provide oral consultation to his or her patient or to the
22 patient’s agents in all care settings;

23 (1) Upon request; or

24 (2) Whenever the pharmacist deems it warranted in the exercise of his or her

25 ² Although the court relied heavily on a law review article which suggested a percentage of
26 75-80%. *Sanderson*, 950 F.Supp. at 992, fn. 11.

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professional judgment.

(b) (1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient’s agent in any care setting in which the patient or agent is present;

(A) Whenever the prescription drug has not previously been dispensed to a patient. . .

(c) When oral consultation is provided, it shall include at least the following:

. . .(2) precautions and relevant warnings, including common or severe side or adverse effects or interactions that may be encountered.
. . .

California Code of Regulations § 1707.2. There are other regulations which pertain to the labeling and selling of prescription drugs.

Thus, plaintiffs should be permitted to amend the master complaint to allege these specific causes of action against the pharmacists for negligence, negligence *per se*, Violation of Business & Professions Code § 17200, and Violation of Business & Professions Code § 17500.

D. THE COURT SHOULD ALLOW PLAINTIFFS TO AMEND TO NAME THE SERVIER DEFENDANTS

On November 13, 1998, the Hon. Louis C. Bechtle, Jr. in *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Products Liability Litigation*, MDL Docket No. 1203 denied without prejudice defendant Les Laboratories Servier’s Motion to Dismiss for Lack of Personal Jurisdiction and for *Forum Non Conveniens*. Pretrial Order No. 373. That order set forth factual allegations against Les laboratories Servier and other Servier defendant alleging who manufactured, licensed, sold Redux (dexfenfluramine) and Pondimin (fenfluramine) across the United States. Plaintiffs seek to amend the Master Complaint to make similar allegations against the Servier defendants.

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1 **E. THE COURT SHOULD ALLOW PLAINTIFFS TO AMEND THE COMPLAINT TO**
2 **ADD PHENTERMINE MANUFACTURERS AND CORRECT THE NAMES OF**
3 **PHENTERMINE MANUFACTURERS WHO HAVE ALREADY BEEN NAMED**

4 Since the Master Complaint was filed, plaintiffs learned the identity of another phentermine
5 manufacturer, and seek to substitute it in the place of a Doe defendant. This defendant is Rhone-
6 Poulenc Rorer, Inc.

7 Additionally, plaintiffs seek to correctly identify defendant Eon Laboratories Manufacturing,
8 Inc. as named in the Master Complaint to Eon Labs Manufacturing, Inc.

9 **IV.**

10 **CONCLUSION**

11 For the reasons set forth above, and for good cause, the Court should allow plaintiffs to
12 amend the Master Complaint as set forth in the [Proposed] First Amended Master Complaint.

13 Dated: December __, 1998

COTCHETT, PITRE & SIMON

14 By _____
15 NANCY L. FINEMAN
16 On Behalf of Plaintiffs' Executive Committee

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