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8 SUPERIOR COURT OF CALIFORNIA
9 COUNTY OF LOS ANGELES
10

11 Coordination Proceeding)
Special Title (Rule 1550(b)))

JUDICIAL COUNCIL COORDINATION
PROCEEDING NO. 4032

12 DIET DRUG CASES)
13)

**PHARMACY DEFENDANTS' NOTICE
OF DEMURRER AND DEMURRER TO
PLAINTIFFS' AMENDED MASTER
COMPLAINT; MEMORANDUM OF
POINTS AND AUTHORITIES**

14 _____)
THIS DOCUMENT RELATES TO:)

15 ALL ACTIONS)
16)

Date: April 9, 1999
Time: 10:00 a.m.
Dept: D

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19 TO ALL PARTIES AND TO THEIR ATTORNEYS OF RECORD:

20 PLEASE TAKE NOTICE that on Friday, April 9, 1999 at 10:00 a.m., or as soon
21 thereafter as counsel may be heard in Department D of the above-entitled Court, located at
22 12720 Norwalk Blvd., Third Floor, Norwalk, California, Pharmacy Defendants in this coordinated
23 proceeding including, but not limited to, Rite Aid Corp.; American Drug Stores, Inc., d/b/a Sav-On
24 Drugs; Costco Pharmacy; Shopco, Inc.; Price Rite Pharmacy; Walgreen Co.; Wal-Mart Stores, Inc.;
25 El Cajon Pharmacy; and Fedco, Inc. (hereinafter "Pharmacy Defendants") will and hereby do demur
26 to the Plaintiffs' Amended Master Complaint (hereafter, the "Amended Complaint") on the
27 following grounds:
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1. Pursuant to Code of Civil Procedure § 430.10(e), Pharmacy Defendants generally demur to the second cause of action in the Amended Complaint for negligence on the ground that it fails to state facts sufficient to constitute a cause of action.

2. Pursuant to Code of Civil Procedure § 430.10(e), Pharmacy Defendants generally demur to the third cause of action in the Amended Complaint for negligence per se on the ground that it fails to state facts sufficient to constitute a cause of action.

3. Pursuant to Code of Civil Procedure § 430.10(e), Pharmacy Defendants generally demur to the eighth cause of action in the Amended Complaint for Bus. & Prof. Code §17200 violation on the ground that it fails to state facts sufficient to constitute a cause of action.

4. Pursuant to Code of Civil Procedure § 430.10(e), Pharmacy Defendants generally demur to the ninth cause of action in the Amended Complaint for Bus. & Prof. Code §17500 violation on the ground that it fails to state facts sufficient to constitute a cause of action.

These demurrers are based on this Notice of Demurrer and Demurrer, the supporting Memorandum of Points and Authorities, attached out-of-state Authorities, and all of the pleadings and evidence on file with the Court in this action, as well as any oral argument made at the hearing of these demurrers.

Dated: March ____, 1999

STONE & HILES, LLP

By _____
Russel D. Hiles
Josephine Lai
Attorneys for Rite Aid Corp.
PHARMACY LIAISON COUNSEL

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Dated: March ____, 1999

BROBECK, PHLEGER & HARRISON LLP

By _____

Gregg A. Farley
Kathleen A. Waters
Attorneys for Costco Pharmacy and Shopko,
Inc

Dated: March ____, 1999

HIGGS, FLETCHER & MACK

By _____

M. Cory Brown
Susan Hack
Attorneys for American Drug Stores, Inc.,
d/b/a Sav-On Drugs

Dated: March ____, 1999

BONNIE STAGG & ASSOCIATES

By _____

Everett McAdoo, Jr.
Attorneys for Price Rite Pharmacy

Dated: March ____, 1999

OWEN & MELBYE

By _____

H. Gregory Nelch
Attorneys for Walgreen Co.

Dated: March ____, 1999

GRECO & TRAFICANTE

By _____

John K. Schlichting
Attorneys for El Cajon Pharmacy

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Dated: March ____, 1999

SNYDER & STROZIER

By _____

Barry Clifford Snyder
Will Tomlinson
Attorneys for Wal-Mart Stores, Inc.

Dated: March ____, 1999

MENDES & MOUNT, LLP

By _____

Ty Vanderford
Yvonne Simon
Attorneys for Fedco, Inc.

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MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

Plaintiffs’ Amended Master Complaint (hereinafter “Amended Complaint”) adds pharmacies as defendants to the Second, Third, Eighth and Ninth Causes of Action alleging, respectively: (i) negligence, (ii) negligence per se; (iii) Bus. & Prof. Code §17200 violations; and (iv) Bus. & Prof. Code §17500 violations. In the Amended Complaint Plaintiffs conclusorily allege that the “Pharmacy Defendants owed a duty to plaintiff to provide warning about the proper use and side effects of fenfluramine, phentermine and/or dexfenfluramine to plaintiff.” (Amended Complaint, ¶ 18). Plaintiffs, however, do not allege any specific acts of wrongdoing attributable to the Pharmacy Defendants, such as that any pharmacy improperly filled out prescriptions or was aware of any obvious errors in the prescription.

Pharmacy Defendants hereby demur to the Amended Complaint on the ground that none of the four causes of action state a meritorious or valid legal claim against the Pharmacy Defendants for the following reasons:

- The California courts have shown an unwillingness to impose liability upon pharmacies that would, in effect, require a pharmacy to substitute or interpose its judgment for that of the prescribing physician.
- Courts across the nation overwhelmingly have declined to extend liability to pharmacies for injuries caused by drugs accurately dispensed according to the terms of facially valid prescription. To impose such liability, courts have reasoned, would be an unnecessary intrusion into the doctor-patient relationship and contrary to the learned intermediary doctrine.
- The California legislature has enacted a statute specifically delineating the two circumstances in which a pharmacist has a duty to inform the customer of harmful side effects of a prescription drug and neither circumstance applies in this fen-phen context. See Calif. Bus. & Prof. Code § 4074(a).
- For the same and additional reasons, Plaintiffs’ Amended Complaint against the

1 Pharmacy Defendants fails to state a claim for “unlawful” or “unfair” business
2 practices under California Business & Profession Code §17200 or §17500. Not
3 only have an overwhelming number of courts determined that a pharmacy cannot
4 be held liable for properly dispensing a prescription drug, but the Unfair
5 Competition statutes have never been used in a context such as this, to apply to a
6 personal injury/product liability case.

7
8 **II. FACTUAL ALLEGATIONS**

9 In the general allegations section of the Amended Complaint, Plaintiffs make no
10 separate allegations as to the Pharmacy Defendants, but merely have added “Pharmacy Defendants”
11 to the previously existing paragraphs 1 and 4 of the original complaint. In the only paragraph
12 raising claims as to the Pharmacy Defendants, Plaintiffs perfunctorily allege that the “Pharmacy
13 Defendants are in the business of selling, assembling, inspecting, marketing, promoting, packaging
14 and/or advertising for sale fenfluramine, phentermine and/or dexfenfluramine to plaintiff. Pharmacy
15 Defendants owed a duty to plaintiff to provide warnings about the proper use and side effects of
16 fenfluramine, phentermine and/or dexfenfluramine (hereinafter ‘fen-phen’) to plaintiff.” (Complaint,
17 ¶18.)

18 More important than these conclusory allegations against the Pharmacy Defendants,
19 however, is what is missing from the Amended Complaint. Specifically, Plaintiffs make no
20 allegation that any pharmacy (1) incorrectly dispensed drugs pursuant to a facially valid prescription;
21 (2) complied with a patently invalid prescription; or (3) dispensed drugs absent a valid prescription.

22 Despite this lack of any alleged wrongdoing, Plaintiffs seek to hold the Pharmacy
23 Defendants liable under four causes of action. Specifically, Plaintiffs raise the following counts
24 against the Pharmacy Defendants:

- 25 • *Second Cause of Action: Negligence.* Plaintiffs summarily allege that
26 “Defendants, [which includes manufacturers, diet centers and pharmacies] and
27 each of them, negligently and carelessly manufactured, designed, formulated,
28 compounded, produced, processed, assembled, inspected, distributed, marketed,

1 labeled, packaged, prepared for use and sold the aforementioned products and
2 failed to adequately test and warn of the risks and dangers of the aforementioned
3 products.” Plaintiffs make no specific allegation whatsoever as to the Pharmacy
4 Defendants.

- 5 • *Third Cause of Action: Negligence per se.* Plaintiffs allege a negligence per se
6 claim based on alleged violations of a variety of federal and state statutes.
7 Plaintiffs erroneously rely on an administrative regulation, 16 CCR §1707.2, as a
8 basis for a negligence per se claim against the Pharmacy Defendants.
- 9 • *Eighth Cause of Action: Violation of Bus. & Prof. Code §17200.* Plaintiffs
10 allege a violation of the Unfair Competition Act claiming that Defendants (which
11 includes manufacturers, health care providers and pharmacies) represented that
12 the Fen-Phen drugs were safe, downplayed health hazards, issued promotional
13 literature and encouraged the use of the drugs. However, Plaintiffs once again
14 make no specific allegation as to the Pharmacy Defendants.
- 15 • *Ninth Cause of Action: Violation of Bus. & Prof. Code §17500.* Plaintiffs allege
16 a violation of the Unfair Competition Act claiming that Defendants (which again
17 includes manufacturers, health care providers and pharmacies) represented that
18 the fen-drugs were safe, falsely advertised the benefits of fen-phen, downplayed
19 health hazards, issued promotional literature and encouraged the use of the
20 drugs. Like the prior counts, Plaintiffs make no specific allegations as to the
21 Pharmacy Defendants.

22 As will be shown by the following, Plaintiffs’ Amended Complaint fails to state any
23 viable claim under the common law or Bus. & Prof. Code §§17200 and 17500 against the Pharmacy
24 Defendants.

25 III.

1 **IV. ARGUMENT**

2 **A. PHARMACIES CANNOT BE HELD LIABLE FOR ACCURATELY**
3 **DISPENSING A LEGAL DRUG IN ACCORDANCE WITH A FACIALLY**
4 **VALID PRESCRIPTION.**

5 **1. California Law Supports Limited Liability for Pharmacies Which**
6 **Accurately Dispense a Prescription Drug.**

7 No California court has ever held, as Plaintiffs suggest, that a pharmacy can be held
8 liable for filling out a valid drug prescription.

9 In the case of Murphy v. E.R. Squibb & Sons, 40 Cal. 3d 672 (1985), the California
10 Supreme Court held that pharmacies cannot be liable under the theory of strict liability for defects in
11 a prescription drug accurately dispensed. In Murphy, the plaintiff brought claims under strict
12 liability against a drug manufacturer and pharmacy for personal injuries allegedly resulting from her
13 mother's use of stilbestrol (DES) while pregnant with plaintiff. See id. at 677. Following a national
14 trend, the Court determined that under California law pharmacies were service providers and,
15 therefore, could not be held strictly liable. See id. at 677-679.

16 Important to the present analysis before this Court, the Court in Murphy wrote that it
17 would be "unfair and burdensome" to expose the pharmacy to strict liability "since it may provide
18 the drug only on a doctor's prescription, *which the pharmacist must strictly follow.*" 40 Cal. 3d at
19 681 (*emphasis added*). This language emphasizes a pharmacy's *inability* to question a physician's
20 decision to prescribe medication. As indicated by the Murphy Court, a pharmacy's duty and
21 obligation is to strictly follow a facially valid prescription.

22 In addition to the deference given to a valid prescription, California has recognized
23 the learned intermediary doctrine and has determined that "in the case of prescription drugs, the
24 duty to warn runs to the physician, not to the patient." Carlin v. Upjohn, 13 Cal. 4th 1104, 1116
25 (1996). Under California law, the manufacturer or supplier of a prescription drug has no legal duty
26 to warn a consumer of the dangerous propensities of its drug as long as adequate warnings are
27 provided to the prescribing physician. See id.; see also Stevens v. Parke, Davis & Co., 9 Cal. 3d
28 51, 65 (1973). Where the California Supreme Court has held that a pharmaceutical manufacturer
does not have a duty to warn a physician's patient, it would be incongruous to hold a pharmacy –

1 which does not make, design or issue warnings with respect to drugs – to such a duty. See Carlin,
2 13 Cal. 4th at 1116; Stevens, 9 Cal. 3d at 65. The physician is the learned intermediary who makes
3 the decision whether or not to prescribe a drug. As will be shown, *infra*, courts across the country
4 have barred such civil liability as to pharmacies based in part on this learned intermediary doctrine.

5 In light of the status of the law in California, pharmacies cannot be held liable under
6 the theories of negligence or negligence per se for injuries allegedly resulting from a validly
7 prescribed and dispensed drug. To hold pharmacies to the standard requested by Plaintiffs would be
8 to interfere in the doctor-patient relationship, force pharmacies to step well beyond their practice or
9 knowledge, and completely redefine the pharmacists’ role. Pharmacies cannot prescribe drugs to
10 their customers. Pharmacies do not know, and are not expected to know, the intricate health history
11 of their customers. Pharmacies cannot chose which drug may, or may not be, most beneficial to the
12 customer. Indeed, Pharmacies have no discretion whether or not to follow a valid prescription, and
13 are unable to deviate from a facially valid prescription. Nor do they design or manufacture the
14 product or issue warnings concerning the product. As a result, pharmacies cannot be held labile for
15 injuries allegedly suffered as a result of ingesting drugs dispensed in accordance with a valid
16 prescription.

17 **2. No Common Law Cause of Action Exists Against Pharmacies in the**
18 **Overwhelming Majority of Jurisdictions that have Considered this**
19 **Precise Question.**

20 Courts across the nation which have considered this precise issue of pharmacy
21 liability have overwhelmingly held that no cause of action lies against a pharmacy which accurately
22 dispenses a drug pursuant to a valid prescription. See McKee v. American Home Products, Corp.,
23 782 P.2d 1045 (Wash. 1989); Coyle v. Richardson-Merrell, Inc., 584 A.2d 1383 (Pa. 1991).¹
24 Indeed, in a recent fen-phen decision in Harrell v. Wyeth-Ayerst Laboratories, No. 98-1194-BH-M
25 (D. Ala., Feb. 1, 1999), faced with the nearly exact issue before this Court, Senior District Judge
26 Hand followed the national trend and held that a pharmacy was not liable for “correctly dispensing a

27 _____
28 ¹ Pursuant to Local Rule 9.4, attached hereto as Exhibit A, in alphabetical order, are all non-California authorities cited in Pharmacy Defendants’ Demurrer to Plaintiffs’ Amended Complaint.

1 legal drug [fen-phen] in accordance with a facially valid prescription from a medical doctor.” (A
2 copy of Judge Hand’s opinion is attached hereto in Exhibit A, at Tab 8, p. 2).

3
4 Moreover, there is a host of cases around the nation uniformly holding that a
5 pharmacy cannot be held liable except for errors in filling out prescriptions. In the leading case of
6 McKee v. American Home Products, Corp., 782 P.2d 1045, plaintiff sued her pharmacy, prescribing
7 physician and drug manufacturer seeking damages for physical and psychological injuries allegedly
8 sustained as a result of her addiction to a prescribed drug which she received from the same
9 pharmacy for over ten years. See id. at 1047. It was undisputed that at no time did the pharmacy
10 warn plaintiff of the possible side effects of extended use of the drug. See id. In a thorough
11 opinion, the Washington Supreme Court surveyed jurisdictions across the country on the issue of a
12 pharmacy’s liability for accurately dispensing a valid prescription and upheld the trial court’s grant
13 of summary judgment dismissing plaintiff’s negligence claims against the pharmacy on the grounds
14 that the pharmacy owed no duty to warn plaintiff of the adverse side effects of long-term use of the
15 drug. See id. at 1046.

16 The Court reasoned that the learned intermediary doctrine, which places the duty to
17 warn the patient on the physician, barred a negligence action against the pharmacist because the
18 patient should look to the physician, not the pharmacist, for information on the prescription drug.
19 See id. at 1049-50. While the pharmacy has a duty to accurately fill a prescription and to be alert
20 for clear errors or mistakes in the prescription, only the doctor knows the myriad of factors that go
21 into deciding the proper medication, proper amount and proper frequency. See id. The pharmacist
22 must fill the prescription as directed and does not have discretion to deviate. See id. at 1049-50.
23 See also Fakhouri v. Taylor, 618 N.E.2d 518, 521 (Ill. Ct. App. 1993) (to impose a duty to warn on
24 the pharmacist would be to place the pharmacists, who does not have the same knowledge of the
25 patient as the doctor, in the middle of the doctor-patient relationship). The Court in McKee
26 explained that:

27 The relationship between the physician-patient-manufacturer applies
28 equally to the relationship between the physician-patient and
pharmacist. In both circumstances the patient must look to the
physician, for it is only the physician who can relate the propensities

1 of the drug to the physical idiosyncrasies of the patient. “It is the
2 physician who is in the best position to decide when to use and how
3 and when to inform his patient regarding risk and benefits pertaining
4 to drug therapy.” . . .

5 Neither the manufacturer nor pharmacist has the medical education or
6 knowledge of the medical history of the patient which would justify a
7 judicial imposition of a duty to intrude into the physician-patient
8 relationship. In deciding whether to use a prescription drug, the
9 patient relies primarily on the expertise and judgment of the physician.

10 McKee, 782 P.2d at 1050-1051, citing W. Keeton, R. Keeton & D. Owen, Prosser and Keeton on
11 Torts, § 96, at 688 (5th ed. 1984).

12 Plaintiff in McKee further argued that the pharmacy should have known that her
13 physician was mis-prescribing the drug in light of its long term use which was contrary to the
14 manufacturer’s literature. 782 P.2d at 1052. The Court, however, refused to hold the pharmacy to
15 such a high standard and determined that the pharmacy does not have a duty to question a judgment
16 made by the physician as to the propriety of a prescription or to warn customers of the hazardous
17 side effects associated with a drug. See id. at 1055-56; see also Nichols v. Central Merchandise,
18 Inc., 817 P.2d 1131, 1133 (Kan. App. 1991) (pharmacy, which was aware that prescribed drug for
19 pregnant plaintiff specifically warned against the risk of bone abnormalities in offspring, had no duty
20 to inform the patient of risks). The Court explained:

21 The alleged negligence in this case, however, involved an exercise of
22 the physician’s judgment in determining whether Plegine was an
23 appropriate drug for McKee’s condition and the length of time she
24 could safely use it. . . .

25 Imposing a duty such as McKee urges would, in essence, require the
26 pharmacist to question the physician’s judgment regarding the
27 appropriateness of each customer’s prescription. Sound policy
28 reasons exist for not imposing such a duty.

McKee, 782 P.2d at 1053.

Likewise, the Supreme Court of Pennsylvania in Coyle v. Richardson-Merrell, Inc.,
584 A.2d 1383, 1386 (Pa. 1991), followed the lead of the McKee analysis and determined that
pharmacies did not have a duty to supply information to customers about risks of allegedly
dangerous drugs where the customer presents a valid prescription. The Court explained that
information about the risks of medicines should be provided by the physician who, after all, is in the

1 best position to evaluate the patient’s needs and risks, and not by the pharmacy. See Id. at 1386.
2 To hold otherwise, the court reasoned, would result in the patient-customer receiving information
3 about the risks of medication “from someone unfamiliar with the patient’s medical condition after
4 those risks had already been weighed by a physician having specific knowledge of the patient’s
5 medical needs.” Id. at 1386. The Court saw “no sound reason for imposing on pharmacists the
6 duty to supply information about the risks of drugs that have already been prescribed.” Id. at 1386.
7 Relying in part on the learned intermediary doctrine, the court explained:

8 Under that rule, information about the risks of medicines is provided
9 to the person who most needs and can best evaluate it – the physician
10 – to be shared with and explained to the patient in the context of his
11 or her individual medical circumstances. If the manufacturer has no
12 duty to directly warn patients of the risks or dangers, it would indeed
13 be incongruous to hold pharmacists to such a duty in the dispensing of
14 drugs.

15 Id. at 1386.

16 Still other courts nationwide have come to the same conclusion that pharmacies
17 should not be liable for properly dispensing a drug pursuant to a valid prescription. For example,
18 the Court in Walker v. Jack Eckerd Corp. Karp, 434 S.E.2d 63, 67-68 (Ga. Ct. App. 1993),
19 performed a survey of pharmacy liability law in the United States and followed the vast weight of
20 authority precluding liability for a pharmacy which accurately fills out a valid prescription. Citing
21 Jones v. Irvin, 602 F.Supp. 399 (S.D. Ill. 1985), the Walker Court explained:

22 “A pharmacist . . . owes the customer the ‘highest degree of
23 prudence, thoughtfulness, and diligence.’” . . . However, “a
24 pharmacist has no duty to warn the customer or notify the physician
25 that the drug is being prescribed in dangerous amounts, that the
26 customer is being over medicated, or that the various drugs in their
27 prescribed quantities could cause adverse reactions to the customer. .
28 . . . Placing these duties to warn on the pharmacist would only serve to
 compel the pharmacist to second guess every prescription a doctor
 ordered in an attempt to escape liability.”

Walker, 434 S.E.2d at 67-68, *citing Jones*, 602 F.Supp. at 402. The Court in Walker cited over a
dozen other cases, including the California Supreme Court decision Murphy v. E.R. Squibb & Sons,
40 Cal. 3d 672, as support for its holding that a pharmacy cannot be held liable for failing to warn a
customer of a drug’s dangerous propensities. See Walker, 434 S.E.2d at 68.

1 In Stebbins v. Concord Wrigley Drugs, Inc., 416 N.W.2d 381 (Mich. Ct. App.
2 1987), the Court similarly explained that:

3 The general rule in Michigan is that a pharmacist is held to a very high
4 standard of care in filling prescriptions and may be held liable for
5 negligence in dispensing a drug other than that prescribed. A
6 pharmacist is generally not held liable for damages resulting from a
7 correctly filled prescription. . . .

8 We hold that a pharmacist has no duty to warn the patient of possible
9 side effects of a prescribed medication where the prescription is
10 proper on its face and neither the physician nor the manufacturer has
11 required that any warning be given to the patient by the pharmacist.

12 Stebbins, 416 N.W.2d at 387-388.

13 Likewise, in Ullman v. Grant, 450 N.Y.S.2d 955, 956 (Super. Ct. 1982), the Court
14 held:

15 A pharmacist is not negligent unless he knowingly dispenses a drug
16 that is inferior or defective. . . . It is not the duty of the defendant,
17 Bayview Pharmacy, to warn the plaintiff of possible side effects in the
18 use of a drug.

19 Ullman, 450 N.Y.S.2d at 956.

20 There are still numerous other decisions that are overwhelmingly in favor of barring
21 liability for a pharmacy that accurately dispensed a drug pursuant to a valid prescription. See
22 Ferguson v. Williams, 399 S.E.2d 389, 393 (N.C. Ct. App. 1991) (pharmacist who properly fills a
23 valid prescription as written by a physician is under no duty to warn a customer about potential risks
24 or dangers associated with taking medication); Gassen v. East Jefferson Hospital, 628 So.2d 256,
25 259 (La. Ct. App. 1993) (pharmacist does not have duty to question judgment made by physician as
26 to propriety of prescription or to warn customers of hazardous side effects or adverse reactions
27 associated with drug); Bichler v. Willing, 58 A.D.2d 331, 334 (N.Y. App. Div. 1977) (consumer
28 should not rely on pharmacist's judgment as to whether drug is fit for purpose but should rely on the
physician who prescribed drug); Raynor v. Richardson-Merrell, Inc., 643 F.Supp. 238, 246 (D. D.C.
1986) (pharmacy owed no duty to warn customer of risks associated with validly dispensed drug);
Adkins v. Mong, 425 N.W.2d 151, 152 (Mich. Ct. App. 1987) (pharmacy has no duty to warn
plaintiff of the potential side effects of the substances it was dispensing in accordance with valid

1 prescriptions); Nevada St. Bd. of Pharmacy v. Garrigus, 496 P.2d 748, 749 (Nev. 1972) (“It is not
2 for the pharmacist to second guess a licensed physician unless in such circumstances that would be
3 obviously fatal.”).²

4 In this fen-phen litigation, Plaintiffs claim that the pharmacies should have warned
5 patients of risks allegedly associated with the fen-phen drug combination. However, even assuming
6 these risks existed, Plaintiffs have not alleged anything to show that the pharmacies could have had
7 any knowledge of, or control over, such risks.

8 For example, Plaintiffs claim that the pharmacies (lumped together with all
9 defendants) somehow should have been aware of animal data from the National Institute of Mental
10 Health suggesting that fen-phen, in combination, damaged brain cells and, moreover, that the
11 defendants (including the pharmacies) should have passed this along to the Plaintiff. (Amended
12 Complaint, ¶ 57). Plaintiffs also claim that all the pharmacies (again lumped together with all
13 defendants) should have been aware of, and passed on to Plaintiffs, results of studies from the Mayo
14 Clinic, New England Journal of Medicine and the American Medical Association which allegedly
15 illustrated increased risks of fen-phen. (Amended Complaint, ¶¶ 65, 67, 68, 71.)

16 To hold the pharmacies to this absurd level of knowledge and liability demanded by
17 Plaintiffs is unsupportable under the law. Plaintiffs in this fen-phen litigation seek to hold the
18 pharmacies to an even higher duty than the duty that the courts in McKee, Coyle and their progeny
19 declined to recognize. In McKee, for example, the Court declined to find such a duty where it was
20 undisputed that the pharmacy was aware from the drug package insert that it was potentially
21 addictive and that the plaintiff was taking that drug prescribed for ten years. McKee, 782 P.2d at
22 1047. Likewise, in Nichols, although the pharmacy was aware from an unambiguous package insert
23 that there was a risk of birth defects with use of the drug while pregnant and was aware that plaintiff
24

25 ² See also the following other cases also holding pharmacists not liable under such
26 circumstances: Kampe v. Howard Start Professional Pharmacy, Inc., 841 S.W.2d 223 (Mo. Ct.
27 App. 1992); Kinney v. Hutchinson, 449 So.2d 696, 698 (La. Ct. App. 1984); Nichols v. Central
28 Merchandise, Inc., 817 P.2d 1131 (Kan. Ct. App. 1991); McLeod v. W.S. Merrell, Inc., 174 So.2d
736, 739 (Fla. 1965); Pysz v. Henry’s Drug Store, 457 So.2d 561, 561-62 (Fl. Ct. App. 1984);
Guillory v. Dr. X, 679 So.2d 1004, 1010 (La. Ct. App. 1996).

1 was pregnant, the court determined that the pharmacy still did not have the duty to warn the patient-
2 customer. Nichols, 817 P.2d at 1132-33. In this fen-phen litigation, the “facts” allegedly known by
3 the defendants in general include animal studies and research from the Mayo Clinic (Amended
4 Complaint, ¶¶ 57, 65) – but there is no allegation showing that these purported risks were ever
5 disclosed to pharmacies or that the pharmacies should be held responsible to warn patients. As the
6 case law from virtually every other state illustrates, there is no legal support for such an
7 extraordinary duty to be imposed on the pharmacies.

8
9 **3. There is No Common Law or Statutory Precedent in California or
the Country at Large Imposing a Duty on Pharmacies to Warn of
Alleged Side Effects of Validly Prescribed Drugs.**

10 Plaintiffs’ reliance on California Code of Regulation §1707.2 as a basis for a
11 negligence per se claim is misplaced.³ This regulation provides that a pharmacist shall provide oral
12 consultation, which includes precautions and relevant warnings, including *common* severe side or
13 adverse effects or interactions that may be encountered “whenever the prescription drug has not
14 previously been dispensed to a patient.” 16 CCR §1707.2 (*emphasis added*). This California
15 regulation does not establish a private right of action, nor does it establish a duty to warn under
16 common law theories of negligence or negligence per se. Indeed, Chapter 9 of the Business &
17

18 ³ 16 CCR § 1707.2, Notice to Consumers and Duty to Consult, provides:

19 (a) A pharmacist shall provide oral consultation to his or her patient or the patient’s
agent in all care settings:

20 (1) Upon request; or
21 (2) whenever the pharmacist deems it warranted in the exercise of his or her
professional judgment.

22 (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
23 the patient or agent is present:

24 (A) whenever the prescription drug has not previously been dispensed to a patient;
or

25 (B) whenever a prescription drug not previously dispensed to a patient in the same
dosage form, strength or with the same written directions, is dispensed by the pharmacy....

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

27 (1) Directions for use and storage and the importance of compliance with directions;
and

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

1 Profession Code illustrates that the California Legislature did not intend to hold pharmacies to the
2 duty to warn that Plaintiffs now seek to impose on pharmacies.

3 In Calif. Bus. & Prof. Code § 4074, the Legislature specifically defined the
4 circumstances in which a pharmacist has a legal duty to inform the patient of harmful effects of a
5 prescription drug. Bus. & Prof. Code § 4074(a) states that “[a] pharmacist shall inform a patient
6 orally or in writing of the harmful effects of a drug dispensed by prescription *if the drug poses*
7 *substantial risk to the person consuming the drug when taken in combination with alcohol or if the*
8 *drug may impair a person’s ability to drive a motor vehicle, whichever is applicable . . .”* Bus. &
9 Prof. Code § 4074(a) (*emphasis added*). As recently as 1996 the California Legislature revised Bus.
10 & Prof. Code § 4074 and chose not to expand the statutory circumstances in which a pharmacist is
11 obligated to warn the person consuming the drug. Indeed, in 1996 the Legislature enacted
12 substantial revisions to Chapter 9 of the Bus. & Prof. Code and did not add the duty requested by
13 the Plaintiffs to any of the statutory provisions. The *only* duty to inform imposed on the pharmacies
14 under California law, therefore, arises when the prescribed drug poses a substantial risk when taken
15 in combination with alcohol or if it may impair a person’s ability to drive a motor vehicle – neither
16 of which applies in this fen-phen context.

17 Moreover, the overwhelming trend in courts nationwide is to decline to recognize,
18 based on similar regulatory provisions, a duty upon pharmacies to inform patients of alleged side
19 effects. The Court in McKee, for example, held that the Washington pharmacy provision, which
20 contained language similar to the provisions the California regulation, did not to create a duty to
21 warn on the pharmacist.⁴ The plaintiff in McKee argued that the Washington state regulation
22 regulating pharmacies created a duty to warn for the pharmacy. The McKee Court disagreed,
23 however, and determined that although “practice of pharmacy” as defined by the regulation includes
24 _____

25 ⁴ The Washington pharmacy provision, RCW 18.64.011(11) reads, in pertinent part, that the
26 “Practice of Pharmacy” “includes the practice and responsibility for: Interpreting prescription
27 orders; the compounding, dispensing, labeling, administering, and distributing of drugs and devices;
28 the monitoring or drug therapy and use . . . the providing of information on legend drugs which may
include, but is not limited to, the advising of therapeutic values, hazards, and the uses of drugs and
devices.” McKee, 782 P.2d at 1051.

1 advising clients on the hazards of drugs, the provision did not create a mandatory duty on all
2 pharmacies to warn customers of all dangers associated with a drug. McKee, 782 P.2d at 1052.

3 Similarly, the Court in Ingram v. Hook's Drugs, Inc., 476 N.E.2d 881, 886-87 (Ind.
4 Ct. App. 1985) determined that the Indiana statute regulating pharmacies did not create a statutory
5 duty to warn of all the hazards associated with the prescription drug.⁵ See also Eldridge v. Eli Lilly
6 & Co., 485 N.E.2d 551, 553-54 (Ill. Ct. App. 1985) (pharmacy regulations did not create a
7 statutory duty to warn by the pharmacists); Harrell v. Wyeth-Ayerst Laboratories, *supra*, No. 98-
8 1194-BHM, p. 2 (Alabama pharmacy regulations did not create duty to warn by pharmacies).

9 Likewise, any expansion of 16 CCR §1707.2 to establish a duty to inform on the
10 pharmacies in the circumstances alleged in the Amended Complaint, would not only run counter to
11 the limited duties to inform legislated in California, but would run counter to the courts across the
12 country which have examined this issue under like regulations. As such, 16 CCR §1707.2 does not
13 provide Plaintiffs with a basis for a negligence or negligence per se claim.

14 Following McKee, Coyle and the overwhelming majority of U.S. Courts, this Court
15 should refuse to extend liability to a pharmacy for injuries allegedly a result of a drug that was
16 accurately dispensed in accordance with a valid prescription. To hold otherwise would require the
17 pharmacy to substitute its judgement for that of the prescribing physician.

18 **B. PLAINTIFFS' AMENDED COMPLAINT FAILS TO STATE A LEGAL**
19 **CAUSE OF ACTION AGAINST THE PHARMACIES UNDER BUS. &**
20 **PROF. CODE. §§17200 AND 17500.**

21 **1. Pharmacists Should Not be Held Liable for Consumer Protection**
22 **Violations Absent a Common Law Violation of a Duty to Warn.**

23 Plaintiffs' claims under Cal. Bus. & Prof. §§17200 and 17500 for unfair competition
24 cannot stand based on the allegations in the Plaintiffs' Amended Complaint. Bus. & Prof. Code
25 §17200 and its companion statute §17500 prohibit unlawful, unfair or fraudulent business acts or

26 ⁵ The Indiana Code evaluated by the court defined the "practice of pharmacy" as "...the
27 responsibility for advising, as necessary, as to the contents, therapeutic values, hazards, and
28 appropriate manner of use of drugs or devices." Ingram, 476 N.E.2d at 884.

1 practices and unfair, deceptive, untrue or misleading advertising. Bus. & Prof. Code §§17200 and
2 17500. Such causes of action, however, cannot apply in a personal injury action based on a product
3 liability action, such as this litigation.

4 Briefly, an “unlawful” business practice or act proscribed by Bus. & Prof. Code
5 §§17200 is any business practice that is forbidden by law. See People v. McKale, 25 Cal. 3d 626,
6 634 (1975). In determining whether an action is “unfair” under B&P §17200, the Court weighs “the
7 utility of the defendant’s conduct against the gravity of the harm to the alleged victim.” State Farm
8 Fire and Casualty Co. v. Superior Court of LA County, 45 Cal. App. 4th 1093, 1103-1104 (1996).
9 Finally, the general test for whether an act is considered “fraudulent” is whether members of the
10 public are likely to be deceived. Committee on Children’s Television v. General Foods Corp., 35
11 Cal. 3d 197, 211 (1983).

12 Plaintiffs allege that Pharmacy Defendants breached a duty to warn Plaintiffs and,
13 consequently, violated §§17200 and 17500. As shown above, however, pharmacies cannot be held
14 to have breached any duty by properly filling out a valid prescription and, therefore, there can be no
15 violation of §§17200 and 17500. Indeed, the pharmacies actions in accurately filling prescriptions
16 are neither unfair nor fraudulent since it is not the duty of the pharmacy to provide the warnings
17 that Plaintiffs claim.

18 As explained by the Coyle Court:

19 [U]nlike the marketing system for most other products, the
20 distribution system for prescription drugs is highly restricted.
21 Pharmacists, as suppliers, do not freely choose which “products” they
22 will make available to consumers in any given instance, and patients,
as consumers, do not freely choose which “product” to buy.

23 Coyle, 584 A.2d at 1386.

24 Likewise, pharmacies do not market prescriptive drugs, but merely dispense those
25 drugs prescribed by a medical doctor.

26 **2.**

1 **3. Bus. & Prof. Code §§17200 and 17500 Does Not Apply in this**
2 **Context.**

3 The foregoing conclusions are also buttressed by the fact that there is no appropriate
4 remedy for the Plaintiffs under California Bus. & Prof. Code §§17200 and 17500. These statutes
5 were enacted to authorize the Attorney General or a private citizen to enjoin (i) unfair or fraudulent
6 business acts or practices and (ii) unfair, deceptive, untrue or misleading advertising. Restitution is
7 also sometimes permitted under the statutes to restore to the public money “which may have been
8 acquired by means of . . . unfair competition.” Bus. & Prof. Code § 17203. However, personal
9 injury damages, such as those sought in this and most other products liability cases, are simply not
10 recoverable under Bus. & Prof. Code §§17200 or 17500. Bank of the West v. Supr. Ct., 2 Cal. 4th
11 1254, 1266 (1992). Indeed, no published California case has been found applying Bus. & Prof.
12 Code §§17200 or 17500 to a personal injury/product liability action.

13 In Klein v. Earth Elements, Inc., 59 Cal. App. 4th 965 (1997), the Court declined to
14 find that the doctrines of strict products liability and breach of implied warranty of fitness supported
15 a claim under Bus. & Prof. §17200. In Klein, the defendant unwittingly distributed contaminated
16 dog food which was recalled upon notice of its contamination. Si at 966. The Court determined
17 that the production of the admittedly defective product, contaminated dog food, did not give rise to
18 a strict liability claim. See id. For the same reason, this Court should not extend Bus. & Prof. Code
19 §§17200 and 17500 to apply to these personal injury/product liability lawsuits filed against
20 pharmacies.

21 Furthermore, nothing in the language or legislative history of Bus. & Prof. Code
22 §§17200 or 17500 indicates that the statutes were intended by the California Legislature to apply to
23 regulate the conduct of pharmacies, especially in this products liability context. Bus. & Prof. Code
24 §§17200 and 17500 authorizes courts to enjoin unlawful, unfair or fraudulent conduct and order
25 restitution of money or property obtained by means of unfair competition. Bus. & Prof. Code
26 §17203. Since damages are not available under Bus. & Prof. Code, Plaintiffs can only be seeking
27 injunctive relief to require this Court to dictate how pharmacies should read, interpret and consider
28 valid prescriptions. This extension of the Unfair Competition Act into the regulated pharmacy field

1 is unsupportable under existing case law interpreting the statutes.

2 Even assuming that Plaintiffs were able to make some valid claim of unfair or
3 fraudulent actions, any restitution claims by Plaintiffs as part of this injunctive relief would only
4 entitle each plaintiff to the relatively small sums of money expended on the prescription provided by
5 the pharmacy. Plaintiff's restitution claims against the pharmacies would, therefore, be equivalent to
6 no more than a small claims action. In addition, Plaintiffs' attempt to have hundreds of parallel
7 individual actions for injunctive relief brought at different times against the pharmacies is simply
8 unmanageable and impractical in practice.

9 For the reasons outlined above, the Court should not extend Cal. Bus. & Prof.
10 §§17200 and 17500 to provide causes of action against the pharmacies.

11 **CONCLUSION**

12 For the foregoing reasons, Pharmacy Defendants hereby respectfully demur to the
13 Second, Third, Eighth and Ninth Causes of Action of the Plaintiffs' Amended Master Complaint
14 which allege, respectively: (i) negligence, (ii) negligence per se; (iii) Bus. & Prof. Code §17200
15 violation; and (iv) Bus. & Prof. Code §17500 violation. To impose upon pharmacists the liability
16 requested by Plaintiffs would, in effect, require a pharmacy to substitute or interpose its judgment
17 for that of the prescribing physician. Moreover, Plaintiffs' Proposed Amended Master Complaint
18 fails to state a legal cause of action against the pharmacies under Bus. & Prof. Code. §§17200 and
19 17500.

20
21 Dated: March ___, 1999

STONE & HILES, LLP

22
23 By _____
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