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San Francisco County Superior Court

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8 WALGREEN CO., and AVENTIS
PHARMACEUTICALS INC.

9 [See last page for additional counsel]
10

11 SUPERIOR COURT OF THE STATE OF CALIFORNIA
12 COUNTY OF SAN FRANCISCO

14 PAUL A. DOWHAL, an individual,
15 Plaintiff,

16 v.

17 SMITHKLINE BEECHAM CONSUMER
HEALTHCARE, LP; MCNEIL CONSUMER
18 PRODUCTS COMPANY, A DIVISION OF
MCNEIL-PPC, INC.; PHARMACIA &
19 UPJOHN, INC.; ALZA CORPORATION;
AVENTIS PHARMACEUTICALS, INC.;
20 PERRIGO COMPANY; COSTCO
COMPANIES, INC.; LUCKY STORES, INC.;
21 RITE AID CORPORATION; SAFEWAY, INC.;
WALGREEN COMPANY; and DOES 3 through
22 300, inclusive,

23 Defendants.
24

Case No. 305893

**[PROPOSED] ORDER GRANTING
DEFENDANTS' SUMMARY JUDGMENT
MOTION AND DENYING PLAINTIFF'S
SUMMARY ADJUDICATION MOTION**

Hearing Date: March 6, 2001
Hearing Time: 9:30 a.m.
Dept: 301
Judge: Hon. David Garcia

Complaint Filed: August 23, 1999
Trial Date: May 29, 2001

25 Pending before the Court are cross-motions for summary judgment and adjudication, filed
26 January 31, 2001. Oral argument on these motions was heard on March 6, 2001. Based on the
27 parties' arguments in their respective papers and during the hearing, Defendants' Summary
28 Judgment Motion on federal preemption is GRANTED and Plaintiff's Summary Adjudication

1 Motion on this issue is DENIED. The Supremacy Clause of the United States Constitution,
2 particularly the doctrine of conflict preemption, bars the relief sought by Plaintiff under Proposition
3 65. Accordingly, because there is conflict preemption, Plaintiff's Summary Adjudication Motion
4 on the "clear and reasonable warning" issue is DENIED.

5 In accordance with Rule 437c(g) of the California Civil Procedure Code, the reasons
6 supporting this determination are as follows:

7 **A. Federal Conflict Preemption**

8 1. This case presents an unusual circumstance: Defendants have been expressly
9 forbidden by the federal government from using the pregnancy warnings on their products that
10 Plaintiff contends are required by state law.

11 2. Over-the-counter drug products, such as those at issue in this case, cannot be sold
12 unless their labels are first approved by FDA and they are marketed in compliance with FDA's -
13 regulations. FDA requires that the content of the warnings that appear on Defendants' products be
14 "clear and truthful in all respects" and stated "in such terms as to render them likely to be read and
15 understood by the ordinary individual . . ." See 21 C.F.R. 331.10(a)(4)(v); see also 21 U.S.C. §
16 355(a) ("No person shall introduce or deliver for introduction into interstate commerce any new
17 drug, unless an approval of an application filed pursuant to . . . this section is effective with respect
18 to such drug."). Unlike most over-the-counter drug products, Defendants' products went through
19 extensive and sequential reviews of product-specific science and medical data by FDA and an
20 independent Medical Advisory Board on the basis of which FDA selected the specific pregnancy
21 warnings to be used on Defendants' products.

22 3. Where, as here, a federal agency requires one thing in accordance with its statutory
23 authority, and a state statute requires another, and where both requirements cannot be satisfied
24 simultaneously, conflict preemption exists and the state requirement must yield. See *Medtronic,*
25 *Inc. v. Lohr*, 518 U.S. 470, 501 (1996) (conflict preemption exists where "Federal Government has
26 weighed the competing interests relevant to the particular requirement in question, reached an
27 unambiguous conclusion about how those competing considerations should be resolved in a

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1 particular case or set of cases, and implemented that conclusion via a specific mandate on
2 manufacturers or producers”).

3 4. This case presents a real conflict, not a hypothetical one. On numerous occasions
4 since 1996, including as recently as March 2, 2001, FDA has instructed Defendants to use a specific
5 pregnancy warning on their products, without “any additional or modified warning” That
6 FDA-mandated warning is different than the warning sought by Plaintiff in this case. Moreover, on
7 three occasions since 1997, FDA has expressly prohibited Defendants from using the Proposition 65
8 “safe harbor” warning on their products — the *only* warning that is, as a matter of law, Proposition
9 65-compliant. Defendants are not required to have an enforcement action brought against them
10 before a conflict exists. See *Grocery Mfrs. of Am., Inc. v. Gerace*, 755 F.2d 993 (2d. Cir.)
11 (upholding conflict preemption without requiring actual violation of federal law or initiation of
12 misbranding action by FDA), *aff’d*, 474 U.S. 801 (1995).

13 5. The fact that FDA has approved a different warning, acceptable to Plaintiff, on a
14 different product (Habitrol) is irrelevant. On July 21, 2000, and again on March 2, 2001, FDA, in
15 response to specific inquiries regarding the Habitrol warning, instructed Defendants that they
16 “must” continue to use the “pregnancy/nursing warning that was approved by the agency as part of
17 their NDA” and stated that “any additional or modified warning may render the product
18 misbranded.” Moreover, as a matter of law, Defendants’ products are different than the Habitrol
19 product referred to by Plaintiff — they are regulated as different products, evaluated as different
20 products by FDA, and subject to warning requirements as different products. See *United States v.*
21 *Generix Drug Corp.*, 460 U.S. 453, 459 (1983).

22 6. The 1997 amendments to the Federal Food Drug and Cosmetic Act, including the
23 express preemption and savings clauses, do not displace conflict preemption. The exemption of
24 Proposition 65 from the *express* statutory preemption created by the 1997 amendments has no
25 bearing on the implied preemption that necessarily results where, as here, there is an actual conflict
26 with a specific FDA requirement relating to the particular product labeling at issue. Nothing in the
27 language, structure, or legislative history of the 1997 amendments suggests otherwise, and there is
28 no indication that Congress intended that, in the unique case of direct conflict between FDA

1 labeling requirements and Proposition 65, the paramount authority of federal law would be
2 nullified. On at least three occasions, the most recent of which was only last month, the United
3 States Supreme Court has held that express preemption and savings clauses like those in this case
4 do not bar the ordinary workings of conflict preemption. *See Buckman v. Plaintiffs' Legal Comm.*,
5 2001 U.S. LEXIS 1701. at **20-21 (Feb. 21, 2001) ("neither an express pre-emption provision nor
6 a saving clause 'bars the ordinary working of conflict pre-emption principles'"); *Geier v. American*
7 *Honda Motor Co., Inc.*, 529 U.S. 861, ___, 120 S. Ct. 1913, 1917-22 (2000) (same); *Freightliner*
8 *Corp. v. Myrick*, 514 U.S. 280, 288-89 (1995) (same).

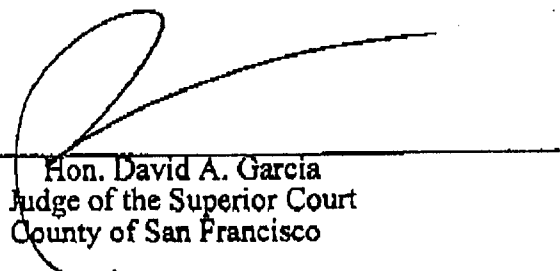
9 7. Requiring Defendants in advertising to use the same warning that FDA has expressly
10 prohibited them from placing on their labels because such warning would be inaccurate would
11 frustrate the purpose of the FDCA and FDA's requirement that label warnings accurately reflect the
12 known health effects associated with a particular product. In June 1998, FDA concluded that the
13 warning sought by Plaintiff would be inaccurate as to Defendants' products. *People v. Cotter &*
14 *Co.*, 53 Cal. App. 4th 1373 (1997), is inapposite. That case dealt with a federal statute -- the
15 Federal Hazardous Substances Act -- whose objective was uniformity in the labels of all paint
16 products. Here, on the contrary, FDA has tailored product-specific warnings to relate to consumers
17 an accurate statement of the health risks-vs.-benefits associated with Defendants' particular
18 products. *See Medtronic*, 518 U.S. at 501.

19 For these reasons, Defendants' Summary Judgment Motion regarding preemption is
20 GRANTED and Plaintiff's Summary Adjudication Motion on the same issue is DENIED.

21 **B. Proposition 65 Clear and Reasonable Warning**

22 Plaintiff also seeks summary adjudication as to whether the pregnancy warning currently on
23 Defendants' products is "clear and reasonable" under Proposition 65. Plaintiff's motion on this
24 issue is DENIED because there is conflict preemption and, even if there were not, there would be a
25 triable issue of fact. **IT IS SO ORDERED.**

26 Dated: 3/9, 2001

27 
28 Hon. David A. Garcia
Judge of the Superior Court
County of San Francisco

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