SUPERIOR COURT OF THE STATE OF CALIFORNIA
FOR THE COUNTY OF LOS ANGELES
DEPARTMENT 311
***Federman v. Qualitest,* BC471059**
Motions for summary judgment/adjudication and class certification

The motion for summary judgment or adjudication generally is denied (although, by stipulation, it is granted as to the claims of negligence and breach of implied warranty, which the plaintiff voluntarily dismisses). The motion for class certification is denied.

I

This class action is about a drug recall by "Qualitest," which is a shorthand label for the defendant pharmaceutical company and its parent. The Qualitest drugs are oral contraceptives marketed as "Gildess" and under other trade names. The contraceptives did not cause physical injuries or unwanted pregnancies, but some packaging was flawed. Once Qualitest discovered the flaws, it investigated the cause and took corrective actions. It also recalled all the Gildess and the other products packaged with the flawed process. The recall covered the nationwide distribution system: wholesalers, retailers, and final consumers. Qualitest incinerated the returns. (Federman Exhibit A, QUALFED000010; Exhibit B, QUALFED000007; Exhibit C, QUALFED000273.) Nationwide, Qualitest recalled 177,976 product units. (Qualitest Exhibit B 10:21.) The record does not show whether wholesalers and retailers were the main, or entire, source of the recalled units. In other words, the record does not show the recall affected any California consumer besides Plaintiff Samantha Federman in any way.

Plaintiff Federman had just finished taking a three month supply of Gildess. Her CVS pharmacy wrote to tell her that the manufacturer was recalling the batch of pills she had purchased. (Fact 9; deposition 45:21-24; 46:18-22.) Federman called CVS and "they [at CVS] said it's as if I hadn't been on birth control for three months." (*Id.* 48:13-17; 83:22-24; 119:18-22.) Federman bought a home pregnancy test, which tested negative. Federman does not know whether her pills or packaging actually were defective. (Fact 11.) She discarded the packaging. (Fact 12.) Federman is suing to recover the money she spent on Gildess and on the pregnancy test. (Fact 17.) Rather than ask for reimbursement, Federman apparently just sued.

II

The motion for summary judgment or adjudication is granted, by stipulation, as to the claims of negligence and breach of implied warranty. The motion is otherwise denied.

A

At this procedural stage, the court takes the facts in the light most favorable to the plaintiff. By Federman's version of events, she has a valid claim for product liability. This requires her to show (1) that Qualitest manufactured or distributed the contraceptives, (2) that the contraceptives contained a defect when Qualitest shipped them, (3) that Federman was harmed, and (4) that the defect was a substantial factor in causing her harm. (CACI 1201.)

Qualitest says there is no evidence Federman personally got a defective package, or that any defect harmed her. The uncontradicted evidence does show Qualitest packaged Federman's pills correctly. But Qualitest's argument neglects both the CVS statement and the money Federman spent on the pregnancy test. These two factors create strict liability for Qualitest.

Qualitest announced a recall when it discovered its admitted glitch. The defect was real, although the probability of any one package containing the error was extremely low. Nevertheless, the probability times the grave potential harm -- the expected value, in coldly statistical terminology -- was high enough to prompt Qualitest to direct pharmacies to contact customers. CVS in turn mailed Federman, who then phoned CVS. The CVS person told Federman that "it's as if I [Federman] hadn't been on birth control for three months." This CVS statement was erroneous. Federman testified (Facts 13 and 14) that she could see the lot number, which meant her packaging was not defective and her pills were fine. (Facts 1 and 10.) Nevertheless, CVS was Qualitest's agent, both actual and apparent. Federman's prudent and predictable response to CVS's erroneous statement was to buy a pregnancy test. (Cf. Qualitest Exhibit C, QUALFED000105 (women could be "at risk for unintended pregnancy").) The test was not free. As between Federman and Qualitest, this unwanted expenditure was Qualitest's fault, as a matter of strict liability.

In sum, Qualitest's manufacturing defect forced Federman to lose money on the pregnancy test. Qualitest is liable to Federman' for the price of her test -- although not for the price of Gildess, which was not defective. (See, e.g., Facts 6-14, Qualitest Exhibit F 3:17-18).

B

In protest, Qualitest cites the economic loss rule. "To apply the economic loss rule, we must first determine what the product at issue is. Only then do we find out whether the injury is to the product itself (for which recovery is barred by the economic loss rule) or to property other than the defective product (for which plaintiffs may recover in tort)." (*Jimenez v. Superior*

Court (2002) 29 Cal. 4th 473, 483.) The product was Gildess. Federman does not complain about injury to Gildess. Rather she worried the defect caused her to become pregnant -- a fear about her body prompting her pregnancy test purchase. The test expenditure is an "involuntary out-of-pocket [loss]" (*id.*), so the economic loss rule does not apply here.

The holding in *Nelson v. Superior Court* (2006) 144 Cal.App.4th 689, 695-699 is irrelevant. That case decided bystanders can recover in strict liability. There were no bystanders here.

Khan v. Shiley (1990) 217 Cal.App.3d 848, 855-857 is also irrelevant. There the court held that "[a] cause of action does not presently exist under any theory premised on the *risk* the [artificial heart] valve *may* malfunction in the future." But Federman is not at risk of future harm. Her claim is for past money spent for a test she did not otherwise want. There is nothing speculative or contingent about her past expenditure.

Similarly irrelevant is *Myers-Armstrong v. Actavis Totowa, LLC* (U.S. Dist. Ct., D.N.CA Apr. 22, 2009, No. C 08-04741 WHA) 2009 U.S. Dist. LEXIS 38112 page *4, 2009 WL 1082026 page *10, where "there [were] no allegations that plaintiff ever had a side effect from the [recalled drug at issue] or that it did not work as intended." The plaintiff in that case had not spent test money to detect drug failure. By contrast, Federman indeed has suffered this economic damage.

Qualitest notes the CVS recall letter explained how to determine if a particular package indeed was defective, and that, according to Federman's testimony, her contraceptives were free of defects. (Facts 9, 10, and 13.) Yet Federman relied on what CVS told her on the phone. At minimum, this is a disputed material fact that precludes summary judgment.

C

Qualitest argues restitution is not appropriate because Federman got the benefit of her bargain. (Motion 10:12-13.) This point cannot withstand Federman's testimony that CVS told her "it's as if I hadn't been on birth control for three months."

III

The motion to certify this class is denied. Qualitest says class certification is improper under *American Honda Motor Co., Inc. v. Superior Court* (2011) 199 Cal.App.4th 1367. (Opposition 10-11.) In reply, Federman ignores *American Honda*. This decision is controlling law, however, and it requires this motion be denied.

American Honda resembles this case in three ways.

First, both *American Honda* and Federman's case involved product defects. In *American Honda*, the alleged problem was that some Acura manual transmissions tended to pop out of third gear. (*Id.* 1369.) In this case, the problem was that Qualitest sometimes -- rarely -- misattached the back sheet to front blister sheet: the back sheet was upside down. The pills go in the blister pockets, and the back sheet seals the blisters closed. Apparently the front plastic sheet is clear but asymmetric, so rotating the back sheet into upside down position changes how the wording on the back sheet lines up with the pill blisters: it "reverses the weekly sequence of pills within the package, which could result in exposure to an unintended dosing sequence resulting in failure of contraception." (Exhibit D, QUALFED 000011.) (The rotation also obscures the expiration date and the lot number.) The skewed labelling thus could cause a woman to take placebo pills during the wrong week of her menstrual cycle, thus risking pregnancy.

Second, in both cases manufacturers voluntarily worked to fix the potential problems, and these efforts alone do not justify class treatment. In *American Honda*, the car maker gave dealers a service update and, later, a technical service bulletin, explaining how to solve the problem. (*American Honda Motor Co., Inc. v. Superior Court*, *supra*, 199 Cal.App.4th 1367, 1369-1370.) In this case Qualitest immediately recalled its product, and on a sweeping basis. *American Honda* held remedial efforts alone do not justify class certification. (*Id.* 1378 ("If a TSB [technical service bulletin] standing alone were sufficient to show a product liability case is proper for class action treatment, then there would be a class action every time a TSB is issued.").) If a recall alone dictated class action treatment, then a class action would follow every recall. That would make manufacturers more reluctant to recall products: a disincentive that would disserve future consumers, who want manufacturers swiftly to cure defects. (Cf. Evid Code 1151, Law Revision Commission Comments ("The admission of evidence of subsequent repairs to prove negligence would substantially discourage persons from making repairs after the occurrence of an accident.").)

Third, in both cases the product error rate was small -- in this case, vanishingly small. The product defect rarely, if ever, caused any real problem. In *American Honda*, the problem plagued less than 4% of the class members. (*American Honda Motor Co., Inc. v. Superior Court*, *supra*, 199 Cal.App.4th 1367, 1377.) Here, the evidence is that California consumers received zero defects. Federman did not receive a defective product. (See Facts 6, 9, 10, 13, and 14.) There is no evidence any California consumer received a Qualitest defect. (See, e.g., Qualitest Exhibit F 3:3-8 & 13-15.)

In consumers' hands, this is an error rate of 0% for this class of consumers. Thus, the record is that this consumer class action is about a nonexistent consumer problem.

There was indeed a manufacturing defect, but Qualitest acted quickly to quarantine and incinerate it. This internal error rate is no gauge of consumer harm, because the company caught and burned up the defect. But even going by this irrelevant internal error rate, that rate is about .01%, which is 400 times smaller than the 4% in *American Honda*.

Page 11 of Qualitest's Exhibit B yields these data:

	INSPECTION	**TOTAL PRODUCTS**	**DEFECTIVE PRODUCTS**
	1	54,654	0
	2	56,154	0
	3	55,746	0
	4	52,800	1
	5	78,768	4
	6	159,120	48
	7	50,724	0
TOTAL		**507,996**	**53**

(See also Federman Exhibit C, QUALFED000268.)

In round numbers, a rate of 53 errors per 507,996 products is a rate one error per 10,000 products, or .01%. The percentage .01% is 400 times smaller than 4%.

This record dooms Federman's motion to certify this class. (*American Honda Motor Co., Inc. v. Superior Court*, *supra*, 199 Cal.App.4th 1367, 1376-1378 (error to certify a class absent "proof of a common defect that is substantially certain to manifest in a future malfunction").) Because the defect affected a vanishingly small percentage of the class, this class "presents too many individualized issues for class treatment." (*Id.* 1378.)

"We are further presented with variances in what caused the [consumer] problems," if indeed there were any consumer problems. (*Id*.)

For instance, Federman got properly packaged pills that the erroneous CVS advice made her distrust. The true cause of her injury (which was the money she spent on the unnecessary pregnancy test) was the incorrect CVS statement that "it's as if I hadn't been on birth control for three months." (Federman deposition 48:13-17; 83:22-24; 119:18-22.) Federman's experience thus seems unusual. Her packaging was not defective. She bought a pregnancy test only because of the unprofessional mistake by the unnamed CVS person. No evidence shows this unprofessional experience was typical. Apparently no other consumer got bad pharmacy advice. (See *American Honda Motor Co., Inc. v. Superior Court*, *supra*, 199 Cal.App.4th 1367, 1379 ("Lee presents no substantial evidence that his UCL claim is subject to common proof. He does not contend that Honda or its dealers made standard or scripted representations to class members.").)

For another instance, the packaging error would have caused real problems if a woman took placebo pills at the wrong time during her cycle. The placebo pills, however, were a different color than the others -- a point about which there is no dispute. Women familiar with the product would not necessarily read the words of instruction all over again, but may simply relied on the pill colors, thus using their own experience and wits to avoid the packaging defect. There is no evidence about this possibility, which presumably would be an individual issue for every class member's claim.

There are other causation "variances." (*Id.* 1378.) If a woman (like Federman) had taken all the tablets and yet had not been sexually active recently, the recall would not concern her. She would not care about past contraceptive effectiveness: it would have been a precaution that turned out to be unnecessary. This would be another issue for individual determination.

Federman does not suggest how to manage these individual issues in a class setting -- without a jury waiver from Qualitest, which it has not offered.

Apart from Federman, there is no evidence any California consumer lost money or value from the recall. Under *American Honda*, individual issues about causation would overwhelm any advantage of class action treatment. The *American Honda* opinion requires denial of this class certification motion.