UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

CHARLES ANTHONY RADER, JR., et al.,

Plaintiffs,

v.

TEVA PARENTAL MEDICINES, INC., et al.,

Defendants.

2:10-CV-818 JCM (RJJ)

ORDER

Presently before the court is defendants Teva Parenteral Medicine, Inc., Sicor Pharmaceuticals, Inc., Sicor, Inc., Baxter Healthcare Corporation, and McKesson Medical-Surgical, Inc.'s (hereinafter "products defendants") motion for summary judgment. (Doc. #34). Plaintiff Charles Anthony Rader, Jr. filed an opposition (doc. #40) and a counter-motion for summary judgment (doc. #41). Products defendants filed a reply in support of their motion and in opposition to plaintiff's motion. (Doc. #46).

This case stems from plaintiff's allegation that he was injured when he received a letter from the Southern Nevada Health District notifying him that because he was given an injection of the generic drug Propofol at the Endoscopy Center of Southern Nevada, he had been "placed at risk for possible exposure to bloodborne pathogens." (Doc. #1-1 Exhibit 1). Plaintiff tested negative for Hepatitis C, Hepatitis B, and HIV, but filed the instant class-action[1] on behalf of similarly situated

[1] Plaintiff's motion to certify class (doc. #26) was filed September 27, 2010, but the parties

James C. Mahan
U.S. District Judge

individuals seeking "reimbursement of the cost of the Propofol procedure" and of "subsequent testing provoked by the ensuing hepatitis outbreak." (Doc. #40).

The complaint (doc. #1-1) alleges claims for relief against the products defendants for (1) strict product liability, (2) breach of implied warranty of fitness for a particular purpose, (3) negligence, (4) violations of the Nevada Deceptive Trade Practices Act, and (5) punitive damages. Plaintiff asserts that products defendants manufactured, sold and distributed the vials of Propofol that were being reused by the endoscopy center. (Doc. #40).

Products Defendants' Motion For Summary Judgment

Summary judgment is appropriate when, viewing the facts in the light most favorable to the nonmoving party, there is no genuine issue of material fact which would preclude summary judgment as a matter of law. *Bagdadi v. Nazar,* 84 F.3d 1194, 1197 (9th Cir. 1996); Federal Rule of Civil Procedure 56(c); *Matsushita Elec. Indus. v. Zenith Radio Corp*., 475 U.S. 574, 587 (1986); *T.W. Elec. Serv., Inc. v. Pacific Elec. Contractors Assn*., 809 F.2d 626, 630 (9th Cir.1987). The purpose of summary judgment is to "pierce the pleadings and assess the proof in order to see whether there is a genuine need for trial." *Matsushita Elec*., 475 U.S. at 586; *International Union of Bricklayers v. Martin Jaska, Inc*., 752 F.2d 1401, 1405 (9th Cir.1985).

The moving party bears the burden of informing the court of the basis for its motion, together with evidence demonstrating the absence of any genuine issue of material fact. *Celotex Corp.v. Catrett*, 477 U.S. 317, 323 (1986). Once the moving party has satisfied its burden, it is entitled to summary judgment if the non-moving party fails to present, by affidavits, depositions, answer to interrogatories, or admissions on file, "specific facts showing that there is a genuine issue for trial." *Celotex Corp.*, 477 U.S. 317, 324; Fed. R. Civ. P. 56(c).

In the present motion for summary judgment (doc. #34), products defendants contend that summary judgment is appropriate on two different grounds; (1) "plaintiff's claims are preempted by federal laws that require the labels and warnings of generic pharmaceuticals such as Propofol to be identical to their branded counterparts," and (2) that since the "United States Food and Drug

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stipulated that the responses were not due until May 23, 2011 (doc. #57).

Administration specifically approved the label and the package insert provided with vials of Propofol, the warnings are adequate as a matter of law."

A. Federal Preemption

With regards to the products defendants' first ground for summary judgment, the Ninth Circuit has held that federal law does not preempt state law failure-to-warn claims against generic manufacturers. *Gaeta v. Perrigo Pharmaceuticals Company.* 630 F.3d 1225, 2011 WL 198420 (C.A. 9 (Cal.)), 11 Cal. Daily Op. Serv. 987, 2011 Daily Journal D.A.R. 1269. Therefore, products defendants' first ground allegedly warranting summary judgment fails.

B. Adequate Warnings As A Matter of Law

In products defendants' second ground for summary judgment, they assert that since the label and packaging of the generic drug Propofol was approved by the Food and Drug Administration, it is adequate as a matter of law. Products defendants contend that since plaintiff's claims "are premised on the theory that the Porpofol vial warnings were inadequate, the current motion is dispositive of all claims." (Doc. #34). The evidence supports a finding that the label and the package inserts on the Profopol warned the users that it was intended for "[s]ingle patient use," that "[c]ontamination can cause fever, infection/sepsis, and/or other life-threatening diseases," and to "not use if contamination is suspected." (Doc. #34 Exhibit B and C). As evidenced by the letter from the Food and Drug Administration (doc. #34 Exhibit A), Profopol was approved and found to be "safe and effective for sale use as recommended in the submitted labeling." Thus, as products defendants contend, there are no genuine issues with regards to these facts.

In light of this, products defendants argue that summary judgment is appropriate. They rely on this court's decision in *Moretti v. Pilva, Inc.,* 2010 WL 3385450 (D. Nev. Aug. 20, 2010), where it rejected the federal preemption argument, but granted summary judgment because; "(1) the labeling (also known as the package insert) for [the generic drug] met the applicable statutory and regulatory requirements of being the same as the labeling for the [r]eference [l]isted [d]rug; (2) the labeling was approved by the FDA; and (3) the labeling warned [of the risk identified by plaintiffs.]" The court agrees with products defendants that all of these elements are seen here, but recognizes

the subsequent decision of the Ninth Circuit in *Gaeta v. Perrigo Pharmaceuticals Company* as it relates to the facts/allegations of the case now before this court.

In *Gaeta v. Perrigo Pharmaceuticals Company,* the court held that despite the approval by the FDA and the compliance with the "same as" requirement, it is "clear that generic manufacturers, just like their name counterparts, *must* take specific steps when they learn of new risks associated with their products," and "*shall* revise their drug labeling to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug." *Gaeta,* 630 F.3d 1231–1232; 21 C.F.R. § 201.57(e) (2004) (emphasis added)(internal quotations omitted). Further, the court held that there are several ways in which a generic manufacturer may amend its labeling or packaging to strengthen the warnings; "(1) the CBE process approved by the Supreme Court...; (2) the "prior approval" process; and (3) by asking the FDA to send "Dear Doctor" warning letters to health care professionals." *Id.*

Here, plaintiff's complaint is premised upon the allegation that products defendants learned of risks associated with the drug, yet failed to "take specific steps" to revise the drug labeling. Specifically, plaintiff alleges not only that products defendants' drug contained inadequate warnings, but that products defendants "had prior knowledge of the risk of infection attendant to dosing multiple patients from a single container of...Propofol," prior knowledge of "actual incidents of hepatitis infection in the ambulatory surgical center environment occurring as a result of such facilities dosing multiple patients from a single container," and that they continued to manufacture, market, and sell the Propofol to the subject endoscopy clinics "in packaged quantities which they knew or should have known were too large to be safely sold to these ambulatory surgical facilities." *Id.*

Additionally, plaintiff asserts that products defendants failed to adequately warn of the risks of infection associated with dosing multiple patients from a single container, "despite the knowledge that the subject endoscopy clinics were likely engaging in precisely that practice due to the inordinately large size of Propofol bottles being used at these facilities." *Id.* Plaintiff presents evidence that products defendants "conducted research and had knowledge that the 10mL vial of

Propofol was the safer vial for use in endoscopy centers[2]" and that selling larger vials to such centers "would lead to the temptation to multi-dose.[3]" Specifically, plaintiff argues that "as far back as 1995, senior representatives from [products defendants] were aware of the dangers of cross contamination caused by multi-dosing or misuses of the designer form of Propofol, Deprivan. *See* Exhibit 18 and 19. Additionally, plaintiff presents evidence via the deposition of Al Ponterdolph, that defendant Baxter received inquiries from the users of its products regarding "if the 10mL vials were multi-dose vials." Exhibit 24.

Despite this knowledge and the user inquiries, plaintiff asserts that products defendants continued to sell 50 mL vials to endoscopy centers and failed to warn the FDA of the information or "request permission to revise their warnings, package inserts, vial design, or marketing materials." Products defendants even concede that there is "recourse available to a generic drug manufacturer wishing to change the label," whereby the manufacturer would simply "furnish adequate supporting information to FDA, which would [then] determine whether the labeling for all products should be modified." (Doc. #46).

As approval by the FDA and compliance with the "same as" requirement do not make the labeling adequate as a matter of law, and there are genuine issues of material fact surrounding whether products defendants knew or should have known that the dosage sold to the endoscopy clinic was of an amount susceptible to multiple dosages resulting in contamination and that multi-dosing was in fact occurring, summary judgment is not appropriate based on the products defendants' second ground. Fed. R. Civ. P. 56; *Gaeta,* 630 F.3d 1231–1232.

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[2] In March of 2002, defendant Baxter conducted marketing research which it shared with Teva, demonstrating that "ideal procedures for the 10mL vial include;...endoscopic procedures," such as here, and that the "biggest advantage is that it will result in less wasted Porpofol." Exhibit 21.

[3] In May of 2000, Gensia n/k/a defendant Teva submitted a suitability petition to the FDA requesting approval of a 100mg/10mL vial (Exhibit 20), stating that "a smaller size is safer in that it may reduce the temptation for dosing multiple patients from a single container thereby reducing opportunities for microbial contamination," and that it would "reduce the temptation and the opportunity for dosing multiple patients form a single drug container."

Plaintiff's Counter-Motion for Summary Judgment

In plaintiff's counter-motion (doc. #40), he contends that summary judgment should be granted in plaintiff's favor regarding defendants' affirmative defense of compliance with federal regulations. Additionally, he asserts that all evidence of federal regulations should be precluded, as presentation of such evidence would mislead the jury on the law. In asserting this, plaintiff is referring to two of his claims for relief, namely (1) strict products liability, and (2) breach of implied warranty of fitness for a particular purpose.

A. Strict Products Liability

The central feature of the doctrine of strict products liability is the potential for imposing liability "although the seller has exercised all reasonable care..." *Shoshone Coca-Cola Bottling Co. v. Dolinski,* 82 Nev. 439, 441, 420 P.2d 855 (1967). Under Nevada law, "the defectiveness of a product is determined solely by the consumer expectation test." *Id.* The court's attention, plaintiff states, should therefore be focused "on the buyer's expectation," and how the product "performed in light of the buyer's reasonable expectation, not upon what the manufacturer did or did not do." *Lenardi v. Ford Motor Company,* 683 P.2d 1097 (Wash. 1984).

Accordingly, plaintiff requests that this court exclude any evidence of the defendants' compliance with FDA regulations. In arguing this, plaintiff suggests that this court should follow the court in *Guadio v. Ford Motor Company,* 976 A.2d 524, 543 (Penn. Sup. 2009), when it excluded evidence of an automaker's compliance with Federal Motor Vehicle Safety Standards, because it would "mislead the jury's attention away from their proper inquiry, namely quality and design of the product in question."

Therefore, plaintiff contends that in a strict liability case, such as this, the focus at trial should be on "the expectations of the ultimate consumer" and "the attributes of the product itself, and not the conduct of the [p]roducts [d]efendants and whether they complied with industry standards," i.e. the FDA regulations. (Doc. #40). Further, he argues that the question at trial "should be is a 50mL vial unsafe for use on a patient in a facility that is solely licensed to conduct endoscopies[,] colonoscopies and other similar short procedures and/or whether the warnings were deficient." *Id.*

Products defendants argue that the plaintiff cannot have it both ways; either the "evidence about FDA regulations and industry practice must be admitted at trial, or [p]laintiff's claims must be dismissed in their entirety as preempted." (Doc. #46); *See generally* FDA Brief. They contend that there are several reasons why the evidence is admissible and denial of the cross-motion is necessary.

With regards to strict products liability, products defendants argue that the evidence is relevant to the "threshold question...of whether Propofol was in fact 'defective' or 'unreasonably dangerous.'" *See e.g., Rivera v. Philip Morris, Inc.,* 125 Nev. 18, 209 P.3d 271, 275 (2009); *Allison v. Merck & Co.,* 110 Nev. 762, 767, 878 P.2d 948, 952 (1994) (both holding that "defective or unreasonably dangerous" is an element that must be shown in a strict liability claim). Therefore, products defendants assert that they are entitled to defend the claim by presenting evidence that would "tend to show that Propofol is safe or that would otherwise tend to show that [p]laintiff cannot carry its burden of proving that Propofol was unreasonably dangerous." (Doc. #46).

Products defendants rely on the Nevada Supreme Court when it held that evidence of industry standards is admissible in products liability cases: "The best way to determine if a defendant should have built a safer product is to let the jury hear all the evidence relating to the course of conduct of both the industry, and the particular manufacturer." *Robinson v. G.G.C. Inc.,* 107 Nev. 135, 142, 143, 808 P.2d 522, 526, 527 (1991). This court agrees with product defendants and the Restatement of Torts, that "compliance with product safety regulations is relevant and admissible on the question of defectiveness." *See* Restatement (Third) of Torts: Products Liability § 4 cmt. e (1998); *O'Neill v. Novartis Consumer Health, Inc.*, 147 Cal. App. 4th 1388, 1394, 55 Cal. Rptr. 3d 551, 557 (2007) (in a design defect and failure to warn case involving drug products containing phenylpropanolamine, the court noted that government standards are relevant and deserve "serious consideration."). However, the court does not find that evidence of compliance is a bar to recovery under strict products liability.

Therefore, the court in not inclined to exclude evidence of products defendants' compliance with FDA regulations with regards to plaintiff's strict liability claim.

B. Breach of Warranty of Fitness For A Particular Purpose

To establish an implied warranty that goods will be fit for a particular purpose under a theory of strict products liability, "the seller must, at the time of contracting, know of a particular purpose for which the goods are required and know that the [consumer] is relying on the seller's skill or judgment to select or furnish suitable goods." *Piotrowski v. Southworth Prods. Corp.,* 15 F.3d 748, 752 (8th Cir. 1994). Plaintiff contends that evidence that products defendants' generic drug Porpofol was approved by the FDA should not be admissible, because "proof of compliance with governmental standards is no bar to recovery on a breach of warranty theory." *Reid v. Eckerds Drugs, Inc.,* 40 N.C. App. 476, 483, 253 S.E. 2d 344 (1979); *Gottdanker v. Cutler Labratories,* 182 Cal. App. 2d 602, 6 Cal. Rptr. 320 (1960).

Plaintiff asserts that such evidence is not only irrelevant to the breach of warranty claim, but the affirmative defense of compliance is not permissible. Products defendants rebut this argument by relying on *Goodman v. Wenco Foods, Inc.,* 333 N.C. 1, 17, 423 S.E.2d 444, 452 (1992), where the court stated that "[p]roof of compliance with government standards is no bar to recovery on a breach of warranty theory; although such evidence may be pertinent to the issue of the existence of a breach of any warranty, it is not conclusive." As with the strict liability claim, the court agrees that proof of compliance is not a bar to recovery, but is nonetheless admissible evidence.

In addition to the claims discussed above, products defendants address the relevant nature of the evidence of compliance with regards to the remaining claims for relief for (1) violations of the Nevada Deceptive Trade Practices Act, and (2) punitive damages. First, they contend that the "knowingly" aspect of the alleged misrepresentations necessarily requires the admission of evidence of their "understanding of the regulatory framework and its attendant obligations and limitations." *See also* Nevada Revised Statute § 598.0915 (defining deceptive trade practice).

Second, with regards to the punitive damages sought, products defendants assert that the evidence is relevant in connection with the question of whether the conduct rises to the level of "oppression, fraud, or malice." *See* Nev. Rev. Stat. § 42.005(1) (defining oppression, fraud, and malice). Specifically, whether the products defendants acted with the requisite level of malice needed

to permit a jury to even consider an award of punitive damages. *Cf. Countrywide Home Loans v. Thitchener,* 129 P.3d 243, 252058 (Nev. 2008). In addition, products defendants argue that the evidence is admissible and relevant "to assist the jury (assuming *arguendo* that a jury finds liability and malice) in determining the appropriate level of punitive damages to award." (Doc. #46).

The court agrees with products defendants, that since the claims against them involve their knowledge, the reasonableness of their actions, and the fraudulent or malicious intent behind their actions, evidence of compliance with FDA regulations is admissible.

Accordingly,

IT IS HEREBY ORDERED ADJUDGED AND DECREED that defendants Teva Parenteral Medicine, Inc., Sicor Pharmaceuticals, Inc., Sicor, Inc., Baxter Healthcare Corporation, and McKesson Medical-Surgical, Inc.'s motion for summary judgment (doc. #34) be, and the same hereby is, DENIED.

IT IS FURTHER ORDERED that plaintiff Charles Anthony Rader, Jr.'s counter-motion for summary judgment (doc. #41) be, and the same hereby is DENIED in part and GRANTED in part. Products defendants may present evidence of compliance with FDA regulations, but such evidence does not conclusively bar recovery of plaintiff's claims.

DATED June 20, 2011.

James C. Mahan

UNITED STATES DISTRICT JUDGE