UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

WILLIAM MILLER, as Administrator of the Estate of CORNELL PHILLIPS, Plaintiff,	:	Case No. 3:08-cv-402
	:	Judge Timothy S. Black
vs.	:	
ALZA CORPORATION, *et al.*, Defendants.	:	

DECISION AND ENTRY GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT IN PART AND DENYING IN PART (Doc. 19)

This civil case is presently before the Court on the Motion of Defendants, ALZA Corporation ("ALZA") and Sandoz, Inc. ("Sandoz"), requesting summary judgment on all of Plaintiff's claims pursuant to Fed.R.Civ.P. 56. (Doc. 19). Plaintiff filed a Response to Defendants' Motion (Doc. 46) and Defendants filed a Reply Memorandum. (Doc. 48). The matter is now ripe for decision.

I. FACTS

This case concerns the death of 51 year-old Cornell Phillips. At the time of his death, Phillips was using a fentanyl patch manufactured by Defendant ALZA and distributed by Defendant Sandoz. Fentanyl patches are prescription pain patches designed to deliver fentanyl through a user's skin.[1] (Doc. 21-1). Fentanyl is a very powerful narcotic drug that is used to treat persistent moderate to severe chronic pain. (Doc. 21-1). Fentanyl is 80 times more potent than morphine by weight and "has a very narrow therapeutic band, meaning the difference between a therapeutic [and] a lethal dose is small[.]" (Doc. 46-4).

[1] Fentanyl patches were approved by the Food and Drug Administration ("FDA") as a safe and effective prescription under the brand name Duragesic®.

The patches Phillips wore at the time of his death contain fentanyl gel in a reservoir between a layer of impermeable polyester backing and a semi-permeable layer of ethyl-acetate vinyl ("EVA") film. (Doc. 21-1). The semi-permeable layer is placed on the patient's skin, and, following application, patches are intended to continuously deliver the requisite dose of fentanyl to the patient's bloodstream over a 72-hour period. (*Id.*) However, Plaintiff alleges that the reservoir design fentanyl patches Phillips wore at the time of his death were known by Defendants to leak as a result of seal integrity defects. (Doc. 1). Further, Plaintiff alleges that, despite proper use, non-leaking reservoir design fentanyl patches were known to "produce levels of fentanyl in patients above the intended and designed level." (Doc. 1).

Before his death, Phillips suffered from chronic pain due to several medical conditions, including chronic intestinal pain and osteoarthritis. (Doc. 32). In 2006, Phillips developed a malignant tumor in his nasopharynx[2] and was diagnosed with nasopharyngeal carcinoma. (*Id.*) During radiation treatment for this cancer, Phillips began to suffer from mucositis, which caused him significant pain. (*Id.*) Phillips rated the pain as a 9 on a scale of 10, and described the pain as "swallowing cut glass." (*Id.*)

In June 2006, Phillips was referred to Dr. E. Ronald Hale after being diagnosed with nasopharyngeal cancer. During the course of treatment, Dr. Hale prescribed Phillips a 25 micrograms per hour ("mcg/hr") fentanyl patch for pain on approximately July 25,

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[2] According to Dr. Hale, "[t]he nasopharynx is the top portion of the airway above the throat, directly behind the nasal vestibule and the nasal cavity." (Doc. 32).

2006. (*Id.*) In August 2006, Dr. Hale increased the dose of the fentanyl patch to 50 mcg/hr by instructing Phillips to use two 25 mcg/hr patches simultaneously. (*Id.*) Phillips' dosage was thereafter increased to 75 mcg/hr, and later increased again to 100 mcg/hr. (*Id.*) According to Dr. Hale, on or about October 22, 2006, Phillips' hematology doctor, Dr. Abuerreish, increased the dosage to 125 mcg/hr. (*Id.*)

On November 6, 2006, Phillips was taken to the Miami Valley Hospital after calling 911. (Doc. 42). He died later that afternoon after attempts to revive him failed. Following his death, Phillips was examined by the Montgomery County, Ohio coroner's office. (Doc. 21-4). Toxicology tests revealed that Phillips had a postmortem fentanyl blood level of 13 ng/mL, well above the expected level from the dosage Phillips used at the time of his death. (*Id.*) After a complete autopsy, Dr. Russell L. Uptegrove, M.D., Forensic Pathologist Deputy Corner of Montgomery County, Ohio, concluded that Phillips died as a result of "fentanyl intoxication." (*Id.*)

Plaintiff, William Miller, administrator of Phillips' estate, filed this wrongful death action asserting statutory product liability causes of action, including: (1) a manufacturing defect claim pursuant to O.R.C. § 2307.74; (2) a marketing defect claim pursuant to O.R.C. § 2307.76; (3) a design defect claim pursuant to O.R.C. § 2307.75; and (4) a failure to conform to representations claim pursuant to O.R.C. § 2307.77. (Doc. 1). Plaintiff also sets forth claims of negligence, negligent misrepresentation, breach of the implied warranty of fitness, breach of express warranty and a claim titled "deliberate, intentional, reckless and/or malicious conduct." (*Id.*) In addition to compensatory damages, Plaintiff's prays for punitive damages.

II. STANDARD OF REVIEW

A motion for summary judgment should be granted if the evidence submitted to the Court demonstrates that there is no genuine issue as to any material fact and that the movant is entitled to summary judgment as a matter of law. Fed.R.Civ.P. 56; *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-248 (1986).

"Summary judgment is only appropriate 'if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.'" *Keweenaw Bay Indian Comm. v. Rising*, 477 F.3d 881, 886 (6th Cir. 2007) (quoting Fed. R. Civ. P. 56(c)). "Weighing of the evidence or making credibility determinations are prohibited at summary judgment - rather, all facts must be viewed in the light most favorable to the non-moving party." *Id.*

Once "a motion for summary judgment is properly made and supported, an opposing party may not rely merely on allegations or denials in its own pleading; rather, its response must - by affidavits or as otherwise provided in this rule - set out specific facts showing a genuine issue for trial." Fed. R. Civ. P. 56(e)(2).

III. ANALYSIS

Defendants move for summary judgment on all claims asserted by Plaintiff. With regard to Plaintiff's product liability claims, Defendants assert: (A) that Plaintiff's failure to warn/inadequate warning claims must fail because the prescribing doctor

unequivocally testified that he would have still prescribed the fentanyl patch despite the warnings advocated by Plaintiff, and because Plaintiff have no proper expert testimony regarding the adequacy of the warnings; (B) Plaintiff's design defect claim must fail because an allegedly leaking patch is not a design defect, and, regardless, Ohio law shields drug manufacturers from design defect claims if they warn of the dangerous aspect of the drug; (C) Plaintiff's manufacturing defect claim must fail because there is no evidence, either direct or circumstantial, sufficient to show that any patch used by Phillips actually leaked; and (D) Plaintiff's failure to conform to representations claim must fail because Plaintiff does not identify representations to which the patches failed to conform.

Defendants also move for summary judgment on Plaintiff's claims of negligence, negligent misrepresentation, breach of warranty claims, claims alleging misrepresentations to the U.S. Food and Drug Administration ("FDA"), and Plaintiff's request for punitive damages.

A. FAILURE TO WARN

Plaintiff's failure to warn claim is premised on the assertion that Defendants failed to warn of the risk of overdose "by leaking or otherwise[.]" (Doc. 1). Defendants challenge Plaintiff's failure to warn claim, arguing that: (1) there is no genuine issue of fact regarding the lack of causation because Dr. Hale would have prescribed despite the warnings advocated by Plaintiff; and (2) Plaintiff's proposed warnings experts are not physicians and cannot testify regarding the adequacy of prescription drug warnings.

Pursuant to O.R.C. § 2307.76, inadequate warnings or instructions render a product defective if:

> at the time of marketing if, when it left the control of its manufacturer, both of the following applied:
>
> (a) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages;
>
> (b) The manufacturer failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm.

To prove a "failure to warn" claim, plaintiffs must prove: "(1) a duty to warn against reasonably foreseeable risks; (2) breach of this duty; and (3) an injury that is proximately caused by the breach." *Graham v. Am. Cyanamid Co.*, 350 F.3d 496, 514 (6th Cir. 2003).

With regard to prescription drugs, a manufacturer's duty is discharged "if the manufacturer adequately warns the patient's doctor of those risks." *Id.* (citing O.R.C. § 2307.76(C)). Further, "[w]hen a plaintiff alleges that the warning given to a prescribing physician is inadequate, the plaintiff must prove his claim through expert medical testimony." *Id.*

1. Warnings Advocated by Plaintiff

Initially, the Court finds it necessary to identify the warnings Plaintiff argues should have been given to fully, properly and adequately warn of foreseeable risks. In

this regard, Plaintiff cites the opinions of: (1) James C. Morrison (Doc. 46-34), a purported expert in FDA drug regulations and labeling; and (2) the declaration of Dr. Kenneth R. Laughery (Doc. 46-35), a Ph.D. in psychology and a certified human factors professional. (Doc. 34).

James Morrison's report accompanying his declaration essentially proposes two warning deficiencies: (1) a failure to warn that all patches need to be checked by the end user for leaking seals;[3] and (2) a failure to warn of the danger of death from appropriate use of the patch. (Doc. 46-34). With regard to the "failure to warn of the danger of death from appropriate use," Morrison testified that:

> it seems appropriate to warn of a situation which I don't believe is - - covered here, um, where patients who have been taking the drug, who are, you know, opiate tolerant and all of that, can suddenly, um, um, develop high levels, high blood levels of fentanyl, and therefore should be warned that if they get any symptoms of, and then list the symptoms, the - - the dizziness, the mental confusion, the - - the depressed breathing and so forth, to take off the patch and go to an emergency room.

(Doc. 44).[4]

Dr. Laughery expressed two similar opinions regarding the inadequacy of the Package Insert warnings or complete failure to warn, opining that the Package Insert (Doc. 21-1) failed to address the following:

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[3] The Package Insert cited by both parties states that patients should be advised that "[t]he fentanyl transdermal system patch should not be used if the seal is broken, or if it is altered, cut, or damaged in any way prior to application. This could lead to the rapid release of the contents of the fentanyl transdermal system patch and absorption of a potentially fatal dose of fentanyl." (Doc. 21-1).

[4] The deposition of Morrison referenced was taken in the case captioned *Robert Auburn v. Johnson & Johnson, et al.*, No. 2008-00008440, that was or remains pending in the Superior Court of California, Sacramento County.

> Even when the patient is a proper candidate for the patch and when it is being used as prescribed, there is a hazard of high levels of fentanyl leading to severe or catastrophic consequences, including death.
>
> It is possible that the reservoir patches can be present with or can develop leaks that lead to hazardous levels of fentanyl with severe or catastrophic consequences, including death.

(Doc. 46-35). In addressing the "hazard of high levels of fentanyl," Dr. Laughery testified:

> I would use the information in the figure and the table that we've talked about at length today that talks about fentanyl levels in the blood[5] with 100 microgram patches and use that as a starting point to make clear that the maximum experienced in that data that's presented there is not a maximum that can he experienced even in circumstances when the patient's a proper candidate and the patch is being used as prescribed, that you can get levels of fentanyl -- fentanyl which exceed that, the 6.1. And I wouldn't leave it in the table for the physician to do the calculations and figure out that 6.1. I would be explicit about all of that, that the information that they ***need*** is that with the proper candidate and being used as prescribed, you can get levels of fentanyl in the blood that can be an overdose and can be fatal.

(Doc. 34) (Emphasis added).[6]

Finally, Plaintiff's expert, Dr. Prausnitz, testified that he ruled out a number of potential explanations for the high fentanyl levels found in decedent's blood postmortem, including the possibility that such level was the normal level achieved by normal use of a non-defective patch by Phillips. (Doc. 51-1). Specifically:

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[5] Notably, Dr. Laughery admitted that he has no expertise to testify "whether or not it is important to prescribing physicians that the patch attain a certain blood fentanyl level." According to Dr. Hale, he never tests for specific fentanyl levels in patients. (Doc. 32). Further, whether or not a patch actually administers a specific fentanyl level in a patient's blood is "irrelevant" to his prescribing decisions. (*Id.*) Further, according to Dr. Hale, he would never "have occasion to read" the fentanyl level tables referenced in the Package Insert. (*Id.*)

[6] The deposition of Laughery reference was taken in the case captioned *Robert Auburn v. Johnson & Johnson, et al.*, No. 2008-00008440, that was or remains pending in the Superior Court of California, Sacramento County.

Q. And then you also considered whether or not the 13- nanogram- per-milliliter level could have [been] caused by a properly functioning patch, correct?

A. Yes.

Q. Did you exclude that possibility?

A. Yes.

(*Id.*) Dr. Prausnitz's ultimate opinion was that a leaking fentanyl patch is the most likely explanation for the high level of fentanyl found postmortem. (*Id.*)

With these advocated necessary warnings, the Court will address Defendants' arguments regarding Plaintiff's failure to warn claims.

2. Proximate Cause

In their first challenge to Plaintiff's failure to warn claim, Defendants argue that Plaintiff cannot prove causation. Defendants argue that there is no evidence of causation because Dr. Hale "testified that he would have prescribed the fentanyl patches to Phillips even if additional warnings were added to the prescribing information as advocated by Plaintiff." (Doc. 20).

Plaintiff bears the burden of establishing a defect and establishing that such defect proximately caused the claimed injury. *See* O.R.C § 2307.73(A)(2). A plaintiff "not only must convince the fact finder that the warning provided is unreasonable, hence inadequate, but he also must establish the existence of proximate cause between the [product] and the fact of the plaintiff's injury." *Hisrich v. Volvo Cars of N. Am., Inc.*, 226 F.3d 445, 450-51 (6th Cir. 2000) (citing *Seley v. G.D. Searle Co.*, 67 Ohio St.2d 192, 423

N.E.2d 831, 838 (1981)). "'In analyzing the proximate cause issue as it relates to failure-to-warn cases,' the Ohio Supreme Court 'divided proximate causation . . . into two sub-issues: (1) whether lack of adequate warnings contributed to the plaintiff's [use of the product], and (2) whether [use of the product] constitute[d] a proximate cause of the plaintiff's injury.'" *Id.*

In Ohio, "where no warning is given, or where an inadequate warning is given, a rebuttable presumption arises, beneficial to the plaintiff, that the failure to adequately warn was a proximate cause of the plaintiff's ingestion of the drug." *Seley*, 67 Ohio St.2d at 200. However, where the evidence demonstrates that "an adequate warning would have made no difference in the physician's decision as to whether to prescribe a drug or as to whether to monitor the patient thereafter, the presumption . . . is rebutted, and the required element of proximate cause between the warning and ingestion of the drug is lacking." *Id.* at 201; *see also Wheat v. Pfizer, Inc.*, 31 F.3d 340, 343 (5th Cir. 1994) (stating that plaintiffs asserting a failure to warn claim must "demonstrate that 'a proper warning would have changed the decision of the treating physician, i.e., that but for the inadequate warning, the treating physician would not have used or prescribed the product").

Thus, where the treating physician unequivocally testifies that s/he would have prescribed the subject drug despite adequate warnings, judgment as a matter of law is appropriate. *See Wheat*, 31 F.3d at 387-88; *see also Motus v. Pfizer, Inc.*, 196 F.Supp.2d 984, 997-98 (C.D. Cal. 2001) (stating that "most cases do not permit a plaintiff to get past

summary judgment where the doctor made unequivocal statements in a pre-trial deposition demonstrating that adequate warnings would not have affected his or her decision to prescribe a drug'"). However, where the evidence does not affirmatively establish that the prescribing physician "would not have behaved differently had he received a different warning[,]" a matter of credibility may exist that is "better made by the finder of fact." *Williams v. Lederle Laboratories*, 591 F.Supp. 381, 387 (S.D. Ohio 1984).

Here, with regard to the risk of leaking patches, Dr. Hale testified unequivocally that he would have prescribed the patch even if specifically warned that "it is impossible to produce patches 100 percent no fentanyl gel leaks[.]"[7] (Doc. 32). He also testified that he would not have advised Phillips of such information and would not have exercised additional precautions in monitoring the course of pain management if so warned. (*Id.*) Accordingly, there is no evidence that a lack of warning regarding the risk of leaking patches caused Phillips' death because, despite any such warning, Dr. Hale testified he still would have prescribed the patch to Phillips. Accordingly, summary judgment on Plaintiff's failure to warn of the risk of leaking patches is proper.

Even assuming Plaintiff's experts opined that the Phillips' high postmortem fentanyl level was most likely caused by normal use of a non-leaking patch, Dr. Hale testified that he would have prescribed the patch to Phillips despite a warning in that

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[7] In fact, when asked whether he would have prescribed the patch to Phillips if specifically warned that "there was a reasonable risk that a person can receive a patch that leaks fentanyl gel," Dr. Hale essentially testified that he already takes such risk into account and already advises his patients accordingly. (Doc. 32).

regard. (Doc. 32). Again, both of Plaintiff's purported warnings experts submit that the Package Insert should specifically warn physicians that patients properly using a non-leaking patch "can get levels of fentanyl in the blood that can be an overdose and can be fatal" (Docs. 34, 44, 46-34, 46-35), even though Dr. Prausnitz eliminated that possibility in the case of Phillips. Nevertheless, Dr. Hale testified that he would have prescribed the patch even if warned that "despite normal use of a non-leaking patch a patient could still receive a fatal doses of fentanyl[.]" (Doc. 32).

In Plaintiff's Response to Defendants' Motion, Plaintiff points to particular testimony from Dr. Hale in an attempt to show that Dr. Hale was not so certain in this regard. Such testimony highlighted by Plaintiff addresses a more specific warning than that advanced by Plaintiff's purported warnings experts, *i.e.*, a warning that despite normal use of the patch, a patient can receive *four to five times* the expected level of fentanyl. Nevertheless, even when asked if he would prescribe the patch to "a patient" if warned "that despite normal use of the patch, a patient could receive a level of fentanyl that was four to five times the [expected] level identified" in the Package Insert, Dr. Hale testified generally that he "may" still prescribe the patch and that he would not "categorically deny using the drug under those conditions." (*Id.*)

In fact, Dr. Hale testified that his decision to prescribe the patch in any particular circumstance requires a risk/benefit decision based on the circumstances in each

particular case.[8] (*Id.*) And in the particular case of Phillips, even if warned "that a 100 microgram per hour patch could potentially not administer 100 micrograms per hour of fentanyl but 400 micrograms per hour of fentanyl[,]" Dr. Hale testified that he still "likely would have [prescribed the fentanyl patch to Phillips], yes." (*Id.*)

Dr. Hale did state at one point in his testimony that he would have more closely monitored Phillips in light of a specific warning that "a patient could receive a blood serum level four to five times in excess of the levels identified" in the Package Insert. Nevertheless, Dr. Hale did testify that he was already monitoring Phillips "on a daily basis because [he] was seeing [Phillips] everyday through radiation treatment and would have treated the potential [fentanyl] intoxication." (Doc. 32). Dr. Hale also testified that he never tests for specific fentanyl levels in patients, and that whether or not a patch actually administers a specific fentanyl level in a patient's blood is "irrelevant" to his prescribing decisions. (Doc. 32).[9] Further, according to Dr. Hale, he would never "have occasion to read" the fentanyl level tables referenced in the Package Insert. (Doc. 32).

Thus, because: Dr. Prausnitz eliminated the possibility that Phillips' high fentanyl level was the normal level achieved by Phillips' use of a non-defective patch; Plaintiff's purported warnings experts do not propose warning that normal use of a non-leaking

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[8] Consistently, when asked at a later point whether he would still prescribe the patch if specifically warned that "a certain number of patches are not going to administer . . . 100 micrograms per hour of fentanyl, but 400 micrograms per hour of fentanyl," Dr. Hale testified that he would "in certain circumstances." (Doc. 32).

[9] Instead, according to Dr. Hale he "specifically advise[s] patients while they are taking the patch, if they have any symptoms, specifically, increase somnolence or the person that is caring for them is noting increased somnolence, that they are to call 9-1-1, report immediately to the hospital by ambulance, and they are to be - - they are to inform the ER doctor that they are taking fentanyl patch so that appropriate treatment could be administered." (Doc. 32).

patch can lead to levels four to five times in excess of the expected blood fentanyl level; Dr. Hale would have prescribed the patches to Phillips even in light of such warnings; Dr. Hale was already monitoring Phillips on a daily basis; and actual levels of fentanyl are "irrelevant" to Dr. Hale's prescribing decisions, the Court finds any alleged uncertainty created by questions regarding a warning that normal use of a non-leaking patch can lead to levels four to five times in excess of the expected blood fentanyl level does not create an issue of fact precluding summary judgment.

In light of the foregoing, Defendants have rebutted any presumption that allegedly inadequate warnings contributed to Phillips' use of the drug, leaving the "required element of proximate cause between the warning and [use] of the drug . . . lacking." *Seley*, 67 Ohio St.2d 192. Therefore, Court finds that Defendants are entitled to summary judgment on Plaintiff's failure to warn claims, and Defendants' Motion for Summary Judgment in this regard is **GRANTED**.[10]

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[10] In light of this disposition, the Court need not address Defendants' contention that Plaintiff's have no proper expert testimony from a physician familiar with prescribing fentanyl patches. "Where the issue is the adequacy of a warning of medical risks, the plaintiff is obliged to present competent medical expert testimony stating that the warning is inadequate to the prescribing physician." *White v. Wyeth Lab., Inc.*, Case Nos. 52108, 52564, 1987 WL 14953, at *5 (Ohio App. Jul. 30, 1987). In *White*, the court cited the general rule that, in the case of pharmaceuticals, "since the warning is directed to physicians, only they or someone with similar expertise concerning pharmaceuticals would be qualified to determine whether or not the warning was adequate." *Id.* (citing *Hill v. Squibb & Sons, E.R.*, , 592 P.2d 1383, 1387-88 (1979)); *see also Graham*, 350 F.3d at 514 (stating that "[w]hen a plaintiff alleges that the warning given to a prescribing physician is inadequate, the plaintiff must prove his claim through expert medical testimony"); *Jones v. Roche Laboratories*, 84 Ohio App.3d 135, 616 N.E.2d 545 (Ohio App. 1992). Undisputedly, neither Morrison nor Dr. Laughery are physicians familiar with prescribing any pharmaceutical, including fentanyl patches.

B. DESIGN DEFECT

Defendants also challenge Plaintiff's defective design claim. First, Defendants assert that Plaintiff's claim is not a design defect claim because an allegedly leaking patch is a manufacturing defect, not a design defect. Second, Defendants contend that they are protected from liability for alleged design defects pursuant to O.R.C. § 2307.75(D) because they provided adequate warnings regarding the unsafe aspects of the patch. Plaintiff contends that he asserts a defective design claim, and that the safe harbor provision in O.R.C. § 2307.75(D) does not apply because alternative designs posed less risk of leakage.

1. Whether Plaintiff Properly Pleads a Design Defect Claim

Defendants argue that "Plaintiff has not properly alleged a design defect claim under Ohio law" because any existence of a leaking patch is not intended in the design, and, therefore, injuries resulting from leaking patches must necessarily result from a defect in manufacturing. In making such an argument, Defendants appear to focus on the adequacy of Plaintiff's pleading rather than Plaintiff's actual proof of a design defect.

Pursuant to O.R.C. § 2307.75, "a product is defective in design or formulation if, at the time it left the control of its manufacturer, the foreseeable risks associated with its design or formulation . . . exceeded the benefits associated with that design or formulation[.]" To prevail on a design defect claim, a plaintiff must show that the design risks outweigh the benefits. *See Patterson v. Central Mills, Inc.*, 112 F.Supp.2d 681, 687 (N.D. Ohio 2000) (citing *Perkins v. Wilkinson Sword, Inc.*, 83 Ohio St.3d 507, 700

N.E.2d 1247 (1998)). In making such a determination, O.R.C. § 2307.75(B) sets forth a number of factors to consider in determining the foreseeable risks associated with the design of a product, and O.R.C. § 2307.75(C) sets forth a number of factors to consider in determining the benefits of a particular design.

Here, in support of the design defect claim, Plaintiff alleges that the risks of the reservoir design outweighed its benefits, especially considering the availability of alternative, safer designs. (Doc. 1). The Court finds that such allegations sufficiently assert a defective design claim under O.R.C. § 2307.75. *See Boroff v. Alza Corp.*, 685 F.Supp.2d 704 (N.D. Ohio 2010) (holding that allegations "that Duragesic 'has been recalled for causing death to users due to an excessive leak of fentanyl, a dangerous narcotic medication, into the skin,' and that this sort of leakage caused the death at issue . . . is enough to give rise to a plausible inference that the foreseeable risks associated with Duragesic's design or formulation outweighed its benefits"). Defendants' contention that the claim in this regard actually alleges a manufacturing defect is without merit, and their Motion in this regard is **DENIED**.

2. Unavoidably Unsafe Defense

Defendants also argue that Plaintiff's defective design claim must fail because they are shielded from such a claim pursuant to O.R.C. § 2307.75(D), which provides that:

> An ethical drug or ethical medical device is not defective in design or formulation because some aspect of it is unavoidably unsafe, if the manufacturer of the ethical drug or ethical medical device provides adequate warning and instruction under section 2307.76 of the Revised Code concerning that unavoidably unsafe aspect.

A product is "unavoidably unsafe" when "in the state of technical, scientific, and medical knowledge at the time a product in question left the control of its manufacturer, an aspect of that product was incapable of being made safe." O.R.C. § 2307.71(A)(16).

Consistent with the statutory definition of "unavoidably unsafe," in a case preexisting the Ohio Products Liability Act, the Supreme Court of Ohio held that "a product is unavoidably unsafe if, at the time of its distribution, there existed no alternative design which would have as effectively accomplished the same purpose or result with less risk." *White v. Wyeth Laboratories, Inc.*, 40 Ohio St.3d 390, 395, 533 N.E.2d 748 (1988). Further, the court held that "a prescription drug, vaccine, or like product is not 'unavoidably unsafe' *per se*[.]" *Id.* Instead, whether a prescription drug "qualifies as 'unavoidably unsafe' . . . is a determination to be made on a case-by-case basis." *Id.*, at syllabus.

Here, the Court finds that the plan language of O.R.C. § 2307.75(D) renders it applicable only to those instances where some aspect of the ethical drug is unavoidably unsafe. Defendants have not asserted that their patch is unavoidably unsafe, and, instead, apparently argue that O.R.C. § 2307.75(D) applies even in instances where an ethical drug is avoidably unsafe.[11] In support of such a contention, Defendants cite the following language in a recent Sixth Circuit case:

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[11] In *Kunnemann v. Janssen Pharm. Products, L.P.*, No. 05 C 3211, 2008 WL 5101116, at *13 (N.D. Ill. Dec. 2, 2008), the court was "persuaded that Duragesic is unavoidably unsafe, but not unreasonably dangerous." There, however, the parties seemingly agreed "that Duragesic was unavoidably unsafe[,]" none of the parties "argued that the risk associated with using the patch outweigh its benefits" and none of the parties "questioned whether the patch is a desirable and useful product."

> According to Ohio law, so long as adequate warning has been provided for a pharmaceutical product, then the manufacturer cannot be strictly liable for design defect under Ohio law, regardless of . . . whether the product was unavoidably dangerous.

Wimbush v. Wyeth, 619 F.3d 632, 637 (6th Cir. 2010) (citing *Frey v. Novartis Pharmaceuticals Corp.*, 642 F.Supp.2d 787, 794 (S.D. Ohio 2009)).

The Court acknowledges the somewhat ambiguous nature of the language in *Wimbush*. However, the Court does not read the statement in *Wimbush* as constituting a holding that the defense set forth in O.R.C. § 2307.75(D) is applicable in cases where the subject prescription drug is *avoidably* unsafe. First, a reading of *Wimbush* does not reveal whether the parties even disputed whether the drug at issue was unavoidably unsafe. *Id.* Further, a review of *Frey*, 642 F. Supp. 2d at 794, which the Sixth Circuit cited in setting forth the aforementioned language, specifically stated that:

> If an adequate warning has been provided for a pharmaceutical product, then the manufacturer cannot be held strictly liable, irrespective of whether there is a causal connection between the plaintiff's use of the drug and the plaintiff's injury, and *despite the fact* that the product is unavoidably unsafe.

(Emphasis added). A review of this language in *Frey* assists in clarifying the language in *Wimbush*.

The Court holds that the defense set forth in O.R.C. § 2307.75(D), by its clear language, applies only to instances where the ethical drug at issue is unavoidably unsafe. Because O.R.C. § 2307.75(D) applies only to ethical drugs that are unavoidably unsafe,

and because Defendants apparently do not argue that their patch is unavoidably unsafe,[12] summary judgment is not proper, and it is denied.

Accordingly, Defendants' Motion with regard to Plaintiff's design defect claim is **DENIED**.

C. MANUFACTURING DEFECT

Defendants move for summary judgment on Plaintiff's manufacturing defect claim asserting that there is no evidence, either direct or circumstantial, to support Plaintiff's theory that any patch used by Phillips actually leaked and contributed to his death. In response, Plaintiff admits that there is no direct evidence of a leaking patch, but argues that the manufacturing defect claim is not limited to a claim of a leaking patch, and nevertheless, Plaintiff asserts that circumstantial evidence creates a genuine issue of material fact as to whether the patch leaked or was otherwise defective in its manufacture. The Court finds that some circumstantial evidence of a leaking patch exists, thereby precluding summary judgment.

Pursuant to O.R.C. § 2307.74, "[a] product is defective in manufacture . . . if, when it left the control of its manufacturer, it deviated in a material way from the design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specifications, formula, or performance standards." As noted above, in proving a products liability claim in Ohio, Plaintiff bears

[12] In fact, Plaintiff has pointed to specific evidence showing that Defendants patch was not unavoidably unsafe, and that safer designs exist and were/are used. Defendants did not object to this specific evidence and presented no argument in opposition in their Reply. (Doc. 48).

the burden of proving a number of elements, chief among those elements is "that . . . there was, in fact, a defect." *Harker v. Black & Decker*, 21 F.3d 427 (6th Cir. 1994).

The Supreme Court of Ohio has stated that the "existence of a defect" is "but one of the three elements necessary for recovery" for an alleged manufacturing defect; Plaintiff must also prove "the claimed defect was present when the product left the hands of the manufacturer and proximately caused the claimed injuries." *State Farm Fire & Casualty Co. v. Chrylser Corp.*, 37 Ohio St.3d 1, 6-7, 523 N.E.2d 489 (1988). Here, Defendants' arguments regarding Plaintiff's manufacturing defect claim focus solely on the alleged absence of evidence that the patch leaked.[13]

"In manufacturing defect cases, the plaintiff has the burden of proving the existence of the defect." *Smitley v. Nissan North America, Inc.*, No. 2:09-cv-148, 2010 WL 3027915 at *3 (S.D. Ohio Aug. 2, 2010) (citing *Bonacker v. H.J. Heinz Co.*, 111 Ohio App.3d 569, 676 N.E.2d 940, 942 (Ohio App.1996)). In Ohio, defects can be proven by circumstantial evidence. O.R.C. § 2307.73(B).[14] "However, such circumstantial evidence must "permit a jury to go beyond speculation and render a judgment in accordance with law." *Smitley*, 2010 WL 3027915 at *4 (citing *State Farm Fire & Cas. Co. v. Chrysler Corp.*, 37 Ohio St.3d 1, 523 N.E.2d 489, 496 (1988)

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[13] At this point, Defendants appear not to challenge whether any leaking defect existed in the product at the time the patches left their control.

[14] O.R.C. § 2307.73(B) provides that "[i]f a claimant is unable because the manufacturer's product in question was destroyed to establish by direct evidence that the manufacturer's product in question was defective or if a claimant otherwise is unable to establish by direct evidence that the manufacturer's product in question was defective, then, consistent with the Rules of Evidence, it shall be sufficient for the claimant to present circumstantial or other competent evidence that establishes, by a preponderance of the evidence, that the manufacturer's product in question was defective[.]"

(abrogated on other grounds by statute)).

Defendants essentially argue that summary judgment in their favor is proper because it is just as likely, if not more likely, that Phillips' postmortem fentanyl levels resulted from "variability of inter-individual rates of absorption, distribution, metabolism, and excretion of opioids in general, and fentanyl in particular. Individuals vary with regard to relevant genetic factors, co-administered rugs, and co-morbidities" rather than an allegedly leaking patch. (Doc. 20). To support this position, Defendants not only point to evidence from their own expert, but point to the testimony of Plaintiff's expert, Dr. Prausnitz, who testified in another case that it is possible for a person using a non-defective and properly functioning patch to have a higher fentanyl level of 16 ng/mL, even using a lower dose of fentanyl patch (100 mcg/hr) than the one Phillips was suing at the time of his death.

However, a review of Dr. Prausnitz's deposition in this case reveals the opinion that the excessive fentanyl level found in decedent's blood was most probably the result of a leaking patch.[15] (Doc. 51-1). In fact, Dr. Prausnitz's opinion rules out a number of other possible explanations for the high fentanyl levels in decedent's blood, namely abnormal physiology, toxicology error, postmortem redistribution, abuse, misuse, incorrect use and the possibility that decedent's postmortem fentanyl level was the normal level achieved by decedent's use of a non-defective patch. (Doc. 51-1). Certainly,

[15] Dr. Prausnitz offers no testimony regarding "the specifics of the leak defect other than the general belief that a leak occurred." (Doc. 51-1).

Defendants point to other evidence contradicting Dr. Prausnitz's conclusion and challenge the credibility of Dr. Prausnitz's ultimate conclusions. However, such issues are reserved for the fact-finder.

Thus, circumstantial evidence is present to create a genuine issue of material fact on the issue of whether decedent, in fact, used a leaking patch. Because Defendants' Motion is targeted solely at the existence of a leaking patch, and because there is a genuine issue of fact as to whether decedent used a leaking patch, Defendants' Motion in this regard is **DENIED**.[16]

D. FAILURE TO CONFORM TO REPRESENTATIONS

Defendants contend that Plaintiff has failed to identify any representations to which the patches failed to conform. In Ohio, "[a] product is defective if it did not conform, when it left the control of its manufacturer, to a representation made by that manufacturer." O.R.C. § 2307.77. Further, "[a] product may be defective because it did not conform to a representation even though its manufacturer did not act fraudulently, recklessly, or negligently in making the representation." *Id.*

To prevail on this claim, Plaintiff must prove that: (1) Defendant "made a representation as to a material fact concerning the character or quality of the" patch; (2)

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[16] Again, unlike defendants in *State Farm*, 37 Ohio St.3d 1, Defendants here present no arguments challenging whether the alleged leak existed at the time the product(s) left Defendants' control. In *State Farm*, the Supreme Court of Ohio found that even though "reasonable minds might differ as to whether the electrical system developed a defect - upon which there is substantial evidence . . . they cannot differ upon the evidence present, absent speculation, as to whether some defect was present when the vehicle left the hands of the manufacturer" because it was "equally likely that the defect arose" during repairs performed after plaintiffs purchased the vehicle. *Id.* at 496-97.

that the patch failed to conform to Defendants' representation; (3) justifiable reliance on Defendants' representation; and (4) that such reliance directly and proximately caused the alleged injuries. *Westfield Ins. Co. v. HULS Am., Inc.*, 128 Ohio App.3d 270, 295, 714 N.E.2d 934 (Ohio App. 1998) (citing *Gawloski v. Miller Brewing Co.*, 96 Ohio App.3d 160, 165, 644 N.E.2d 731 (Ohio App. 1994)); *Barrett v. Waco Internatl., Inc.*, 123 Ohio App.3d 1, 702 N.E.2d 1216 (Ohio App. 1997); *White v. DePuy, Inc.*, 129 Ohio App.3d 472, 718 N.E.2d 450 (Ohio App. 1998).

Defendants' Motion argues that Plaintiff failed to identify any representations made by Defendants, and further failed to show, via expert testimony, that the patch did not conform to such representations. Plaintiff, however, points to representations made by Defendants regarding the maximum blood concentration of fentanyl that would result from using the patches. Further, Plaintiff points to evidence that Plaintiff's blood-concentration of fentanyl at the time of his death greatly exceeded the amounts represented by Defendants. In their Reply (Doc. 48), Defendants offer no rebuttal to the arguments and evidence presented by Plaintiff in this regard. Accordingly, summary judgment on Plaintiff's failure to conform claim is **DENIED.**

E. NEGLIGENCE AND BREACH OF WARRANTY CLAIMS

Defendants argue that Plaintiff's negligence and negligent misrepresentation claims, along with Plaintiff's claims for breach of the implied warranty of fitness and breach of express warranty, have been abrogated by Ohio's Product Liability Act ("OPLA"). Plaintiff concedes that the claims of negligence and negligent

misrepresentation have been abrogated by the OPLA, and, therefore, summary judgment on those claims is proper as a matter of law. *See* O.R.C. 2307.71(B) (stating that Ohio Revised Code "Sections 2307.71 to 2307.80 of the Revised Code are intended to abrogate all common law product liability claims[17] or causes of action"); *see also Stratford v. SmithKline Beecham Corp.*, No. 2:07-cv-639, 2008 WL 2491965, at *5 (S.D. Ohio Jun. 17, 2008).

Further, common law warranty claims have also been abrogated by the OPLA, and therefore, insofar as Plaintiff asserts warranty claims under the common law, those claims have been abrogated by virtue of O.R.C. § 2307.71(B), and summary judgment in favor of Defendants on such claims is proper as a matter of law. *Stratford*, 2008 WL 2491965; *Donley v. Pinnacle Foods Group, LLC*, No. 2:09-cv-540, 2009 WL 5217319, at *4 (S.D. Ohio Dec. 28, 2009).

Here, however, Plaintiff states that the breach of warranty claims are statutory warranty claims under Ohio's codification of the Uniform Commercial Code ("UCC") in O.R.C. Chapter 1302. Plaintiff argues that UCC warranty claims are not abrogated by the OPLA, citing *Miles v. Raymond Corp.*, 612 F.Supp.2d 913, 924-25 (N.D. Ohio 2009). Courts in this District have also determined that UCC warranty claims are not abrogated

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[17] O.R.C. § 2307.71(A)(13) defines a product liability claim as "a claim or cause of . . . that seeks to recover compensatory damages from a manufacturer or supplier for death, physical injury to person, emotional distress, or physical damage to property other than the product in question, that allegedly arose from . . . : (a) The design, formulation, production, construction, creation, assembly, rebuilding, testing, or marketing of that product; (b) Any warning or instruction, or lack of warning or instruction, associated with that product; (c) Any failure of that product to conform to any relevant representation or warranty. "Product liability claim" also includes any public nuisance claim or cause of action at common law in which it is alleged that the design, manufacture, supply, marketing, distribution, promotion, advertising, labeling, or sale of a product unreasonably interferes with a right common to the general public."

by virtue of O.R.C. § 2307.71(B). *CCB Ohio LLC v. Chemque, Inc.*, 649 F. Supp. 2d 757 (S.D. Ohio 2009) (stating that "Plaintiffs' warranty claims can find a basis grounded in the Uniform Commercial Code and therefore are not claims abrogated by the OPLA"); *see also Donley*, 2009 WL 5217319 at *4.

Here, Defendant argues that the allegations in the Complaint do not support Plaintiff's contention that the warranty claims are asserted under R.C. Chapter 1302. Defendants point out that the "Complaint makes no reference – expressly or impliedly – to the UCC or its codification in Ohio[.]" (Doc. 48). The Court agrees with Defendants that nothing in Plaintiff's Complaint indicates that the warranty claims are being pursued under O.R.C. Chapter 1302. Not only does the Complaint not cite Ohio's codification of the UCC, Plaintiff's Response to Defendants' Motion fails to identify the specific UCC sections under which the warranty claims are being pursued. (Doc. 47).

This district has dealt with the failure to specifically state whether warranty claims are asserted under the UCC. In *CBB Ohio*, the court seemingly allowed the UCC claims to stand, only to dismiss them as being time-barred under O.R.C. 1302.98. *CBB Ohio*, 649 F.Supp.2d at 926-27, n15. In *Donley*, however, the court stated:

> Plaintiff's Complaint . . . contained no reference to the Uniform Commercial Code, or to the two statutes he cites in his memorandum contra [i.e., O.R.C. §§ 1302.27 and 1302.28]. The defendants are again entitled to "a short and plain statement of the claim showing that the pleader is entitled to relief". Fed. R. Civ. Pro. 8(a)(2). To the extent that Plaintiff now alleges that he is (and always was) suing under the Uniform Commercial Code, his Complaint failed to state such claims. To the extent that Plaintiff was suing under common-law theories of product liability, Defendants' unrefuted argument that these theories have been statutorially abrogated is correct.

> Plaintiff is free to move to amend his complaint to add claims arising under the Uniform Commercial Code, but he has, as yet, not stated any. The common law product liability claims he did state are barred as a matter of law.

Donley, 2009 WL 5217319, at *4.

Here, Plaintiff fails to cite any portion of O.R.C. Chapter 1302 in the Complaint (Doc. 1) or in the Response to Defendants' Motion. (Doc. 46). In fact, in Plaintiff's Response, Plaintiff merely asserts in conclusory fashion that the claims are UCC claims, not common law claims.[18] Based on *Donley*, and in light of Plaintiff's conclusory arguments in attempting to establish that the warranty claims are UCC claims, the Court finds that summary judgment is proper.

Accordingly, Defendants' Motion with regard to Plaintiff's negligence, negligent misrepresentation and warranty claims is **GRANTED**.

F. CLAIMS OF MISREPRESENTATIONS TO THE FDA

Defendants contend that Plaintiff asserts a claim seeking recovery for purported misrepresentations made by Defendants to the Food and Drug Administration ("FDA").

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[18] Further, Plaintiff's implied warranty claim appears to track the language of O.R.C. § 1302.28, which sets forth the implied warranty of fitness for a particular purpose and states that: "[w]here the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is . . . an implied warranty that the goods shall be fit for such purpose." The term "'particular purpose' differs from the ordinary purpose for which the goods are used in that it envisages a specific use by the buyer which is peculiar to the nature of his business[.]" *See* Official Comment 2 to O.R.C. § 1302.28. On the other hand, "the ordinary purposes for which goods are used are those envisaged in the concept of merchantability and go to uses which are customarily made of the goods in question." *Id.*

Here, a review of the pleadings and the evidence presented in the parties' memoranda reveals that Phillips used the patch to relieve pain. The relief of pain is the ordinary purpose for which the patch was to be used, not some particular purpose "peculiar" to Phillips. Therefore, even if Plaintiff appropriately pled and sought relief under O.R.C. § 1302.28, such a claim seemingly has no merit.

Specifically, Defendants point to language in the Complaint alleging that:

> Defendants fraudulently and in violation of applicable regulations of the FDA, withheld [information] from the FDA known to be material and relevant to the harm that the claimant allegedly suffered or misrepresented to the FDA information of that type.

(Doc. 1). In response, Plaintiff argues that no claim is premised on fraudulent statements to the FDA. However, despite Plaintiff's contention that no such claim is asserted, the Complaint, in the Court's view, clearly asserts such a claim.

Claims asserting fraud on the FDA are preempted by the Food, Drug and Cosmetics Act ("FDCA"). *See Garcia v. Wyeth-Ayerst Laboratories*, 385 F.3d 961, 965 (6th Cir. 2004) (citing *Buckman Co. v. Pls. Legal Comm.*, 531 U.S. 341, 350 (2001)); *see also In re Aredia and Zometa Products Liab. Litig.*, 352 Fed.Appx. 994 (6th Cir. 2009). Here, Plaintiff's tenth cause of action, entitled "Deliberate, Intentional, Reckless, and/or Malicious Conduct," insofar as it is premised on alleged fraudulent withholding of information or making misrepresentations to the FDA, are preempted and are dismissed, with prejudice.

Accordingly, Defendants' Motion in this regard is **GRANTED**.

G. PUNITIVE DAMAGES

Finally, Defendants argue that Plaintiff cannot recover punitive damages in a wrongful death action pursuant to O.R.C. § 2125.02(B), and cite *Rubeck v. Huffman*, 54 Ohio St.2d 20, 23, 374 N.E.2d 411 (1978), wherein the Supreme Court of Ohio held that "punitive damages are . . . not available in a wrongful death action." *See also Estate of*

Beavers v. Knapp, 175 Ohio App.3d 758, 889 N.E.2d 181 (Ohio App. 2008). In response to Defendant's arguments in this regard, Plaintiff "concedes that he is not entitled to punitive damages in this wrongful death case." (Doc. 46).

Accordingly, the Defendants' motion in this regard is **GRANTED**.

IV. CONCLUSION

For the foregoing reasons, Defendants' Motion for Summary Judgment is **GRANTED** with regard to the following claims, which are dismissed: Plaintiff's Failure to Warn/Inadequate Warning Claim asserted pursuant to O.R.C. § 2307.76; Plaintiff's claims of negligence and negligent misrepresentation; Plaintiff's breach of warranty claims; Plaintiff's claims asserting fraud upon the FDA; and Plaintiff's request for punitive damages.

Defendants' Motion for Summary Judgment is **DENIED** in all other respects.

IT IS SO ORDERED.

Date: 12/17/10

Timothy S. Black
Timothy S. Black
United States District Judge