# **UNPUBLISHED OPINION - APPENDIX**

[DO NOT PUBLISH]

**FILED** 

ELEVENTH CIRCUIT JULY 29, 2008 THOMAS K. KAHN

CLERK

# IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT U.S. COURT OF APPEALS

No. 07-12258

D. C. Docket No. 06-80702-CV-KLR

LORI JO BAILEY, as the Personal Representative of the Estate of Chad Beal,

Plaintiff-Appellant,

versus

JANSSEN PHARMACEUTICA, INC., JANSSEN, L.P., et al.,

Defendants-Appellees.

Appeal from the United States District Court for the Southern District of Florida

(July 29, 2008)

Before ANDERSON and SILER,\* Circuit Judges.\*\*

\* Honorable Eugene Siler, Jr., United States Circuit Judge for the Sixth Circuit, sitting by designation.

\*\* Judge Frank M. Hull was a member of the panel which heard oral argument but recused herself following oral argument and did not participate in this decision. The case is decided by a quorum. <u>See</u> 28 U.S.C. §46(d) (2006); 11th Cir. R. 34-2.

PER CURIAM:

This opinion is provided as an appendix to our simultaneously issued published opinion in the above-styled case. Finding the district court erred in part in granting appellee's motion to dismiss, we reverse in part and affirm in part the dismissal of appellant's First Amended Complaint.

### I. BACKGROUND

The decedent, Chad Edgar Beal ("Beal"), died on March 5, 2004, after having received a lethal dose of a pain narcotic, fentanyl, via a transdermal skin patch prescribed to him by his doctor. The prescription patch, Duragesic, was manufactured by defendant Alza Corporation ("Alza") and distributed by defendant Janssen Pharmaceutica, Inc. ("Janssen"), both of which are subsidiaries of the holding company, defendant Johnson & Johnson, Inc. ("Johnson & Johnson"). The patch was sold to Beal at a South Florida store of defendant Walgreen Company ("Walgreen").

Beal underwent spinal surgery two days before his death and was prescribed the Duragesic patch by his doctor to help him manage his post-surgical pain. The patch is designed to release a controlled dose of fentanyl, a powerful opiate, to its wearer over a seventy-two-hour period. Despite the box's warning that the Duragesic patch was "not for acute or postoperative use," Beal's doctor prescribed him the medication.<sup>1</sup> Appellant alleges that the patch malfunctioned and delivered to Beal the entire dose of fentanyl at one time, as opposed to slowly over the seventy-two-hour period. Appellant originally brought this action in state court on behalf of Beal, seeking relief under various tort and contract theories for Beal's wrongful death.

At the time the district court ruled on appellant's motion to remand, which is the subject of our published opinion, the court also dismissed appellant's original (state court) complaint on procedural and substantive grounds. This complaint was a typical "shotgun complaint," and alleged numerous "sub-counts" within each of eight separate counts. For example, Count I of the original complaint, which was, generally, a "strict liability" claim, raised sub-claims A through F: strict liability product defect, strict liability failure to warn, breach of warranty of fitness for a particular purpose, breach of warranty of merchantability, fraudulent misrepresentation, and reckless disregard of unreasonable risk of harm. The district court, in dismissing the complaint without prejudice to permit repleader, held: "The Defendants are entitled to a Complaint containing specific allegations of

<sup>&</sup>lt;sup>1</sup> Plaintiff did not plead facts with regard to what the warning on the box actually said; Defendants described the content of the warning label in their motion to dismiss, Docket No. 9.

their alleged wrongdoing separated into individual counts." District Court Order, Docket No. 30, at 5.

The district court, at the time it dismissed appellant's complaint for repleader, also addressed a number of substantive deficiencies in the complaint. The court noted, chief among the substantive deficiencies, that appellant failed to allege "how, if at all, the patch was defective," id. at 5, and whether the defect came from the "product's design or manufacturing process"—or, in other words, whether any purported defect occurred on the assembly line or in the design process. Id. at 6. Further, the original complaint, the district court held, failed to adequately plead strict liability for failure to warn because it did not make a factual allegation that "the warnings were inadequate in light of the generally recognized and prevailing scientific and medical knowledge at the time of manufacture." Id. at 7. Nor did the complaint allege facts that might establish that the warnings to Beal's prescribing physician had been inadequate.<sup>2</sup> Appellant's claims for breach of implied warranties failed for lack of privity between the consumer and all Defendants other than Walgreen, the retailer who sold the product to Beal. The claim for breach of implied warranty of merchantability against Walgreen

<sup>&</sup>lt;sup>2</sup> Florida law applies the learned intermediary doctrine whereby the duty to warn runs to the physician and not the patient. <u>See Buckner v. Allergan Pharm., Inc.</u>, 400 So. 2d 820, 822 (Fla. 5th DCA 1981).

nevertheless failed because the complaint contained "no allegations that the patch failed during its use in its reasonable and usual manner," nor did the complaint allege that the product was unmerchantable at the time of sale. <u>Id.</u> at 11.

Following the court's order dismissing appellant's original complaint without prejudice, appellant filed an improved and shorter First Amended Complaint, which attempted to overcome the procedural and substantive difficulties highlighted by the district court in its November order. Although the First Amended Complaint did not expressly commingle the claims in the same manner as the original complaint (i.e., not as express sub-claims), the district court still found the First Amended Complaint infirm for procedural and substantive errors not remedied following the earlier dismissal. Among the procedural errors, the court found the allegations "wholly conclusory." District Court Order, Docket No. 42, at 4. As a result of a typographical error, the first sentence of each count in the First Amended Complaint read: "Plaintiff adopts and realleges the foregoing paragraphs of this complaint as if fully set forth herein."<sup>3</sup> First Amended Complaint, Docket No. 31, at 13, 18, 20, 22, 23-24, 25, 27, 28 (emphasis added). In effect, then, each subsequent count incorporated into it the prior counts, as well

<sup>&</sup>lt;sup>3</sup> Appellant recognized below at the hearing on the motion to dismiss and in her brief in response thereto, that there was this typographical error in the complaint.

as the preceding factual allegations. Putting aside this typographical error, however, the district court also determined that the complaint commingled claims, albeit in less obvious ways than creating strict subdivisions within a single count. For example, according to the district court, Count I, which is the "strict liability" count, purportedly raised at least five causes of action against all defendants: (1) design defect, (2) manufacturing defect, (3) failure to warn, (4) alter ego/piercing the corporate veil, and (5) conspiracy. Similarly, Count II, for negligence, purportedly raised several individual causes of action under the rubric of "negligence" against all defendants: (1) negligence, (2) design defect, (3) manufacturing defect, (4) failure to warn, (5) alter ego/piercing the corporate veil, and (6) conspiracy. The district court held that because appellant failed to adhere to its earlier instruction that each defendant was "entitled to a Complaint containing specific allegations of their alleged wrongdoing separated into individual counts," at least in so far as the complaint did not break down claims by defendant into separate counts, that the First Amended Complaint should be dismissed with prejudice.

The district court also, again, found the First Amended Complaint substantively infirm, and ordered its dismissal with prejudice under Fed. R. Civ. P. 12(b)(6). The district court believed that the First Amended Complaint failed to remedy the deficiencies the court had brought to appellant's attention. Among the substantive deficiencies noted by the district court, the amended complaint did not properly allege that the defendants failed to adopt a reasonable alternative design, did not distinguish between design defect and manufacturing defect, and also failed to plead how the warnings on the product were deficient in light of "the generally recognized and prevailing scientific and medical knowledge at the time of the manufacture." District Court Order, Docket No. 42, at 6, 7, 8. According to the district court, Count II, the negligence claim, "contain[ed] no facts establishing how Defendants breached their alleged duty to perform adequate inquiries regarding the cause of the alleged defects, promptly recall the patch at issue, or reduce the danger of injury associated with use of the patch."<sup>4</sup> Id. at 8.

The court ordered dismissal of the First Amended Complaint with prejudice as a result of the procedural and substantive insufficiencies. Appellant brought the instant timely appeal and only challenges the merits of the district court's decision with regard to Counts I, II, and IV—respectively, her strict products liability claim, her negligence claim, and her breach of the implied warranty of merchantability claim against Walgreen. Moreover, with respect to Count I, appellant challenges

<sup>&</sup>lt;sup>4</sup> The court did not expressly discuss substantive deficiencies of Count IV, the implied warranty claim, and we will therefore assume that its dismissal was on procedural grounds.

the district court's decision only with respect to strict liability for design or manufacturing defect and strict liability for failure to warn. Similarly with respect to Count IV, appellant challenges the district court decision only with respect to breach of implied warranty of merchantability.<sup>5</sup>

#### II. STANDARD OF REVIEW

The district court's dismissal with prejudice of the First Amended Complaint for failing to remedy the procedural infirmities identified by the court in its November 2006 order was tantamount to a dismissal pursuant to Rule 41(b), for failing to adhere to a court order. We review dismissals with prejudice pursuant to this Rule for abuse of discretion. <u>Gratton v. Great Am. Commc'ns</u>, 178 F.3d 1373, 1374 (11th Cir. 1999).

The court below also ordered dismissal of the complaint on substantive grounds under Rule 12(b)(6). This Court reviews a dismissal pursuant to Rule 12(b)(6) <u>de novo</u> and applies the same standard as the district court did. <u>Hoffman-Pugh v. Ramsey</u>, 312 F.3d 1222, 1226 (11th Cir. 2002). This Court accepts as true the factual allegations in the complaint and construes them in a light most favorable to the plaintiff. <u>Id.</u> at 1225. However, the complaint's "[f]actual allegations must

<sup>&</sup>lt;sup>5</sup> Any appeal with respect to other aspects of the district court decision which are not thus challenged are deemed abandoned.

be enough to raise a right to relief above the speculative level." <u>Bell Atl. Corp. v.</u> <u>Twombly</u>, \_\_ U.S. \_\_, 127 S. Ct. 1955, 1965 (2007); <u>see also Watts v. Fla. Int'l</u> <u>Univ.</u>, 495 F.3d 1289, 1295 (11th Cir. 2007). "The Supreme Court's most recent formulation of the pleading specificity standard is that 'stating such a claim requires a complaint with enough factual matter (taken as true) to suggest' the required element." <u>Watts</u>, 495 F.3d at 1295 (quoting <u>Twombly</u>, 127 S. Ct. at 1965). This rule does not "impose a probability requirement at the pleading stage." <u>Twombly</u>, 127 S. Ct. at 1965. Instead, the standard "simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence" of the required element. <u>Id.</u> "It is sufficient if the complaint succeeds in 'identifying facts that are suggestive enough to render [the element] plausible."" <u>Watts</u>, 495 F.3d at 1296 (quoting Twombly, 127 S. Ct. at 1965).

### III. DISCUSSION

# A. <u>The Complaint Generally</u><sup>6</sup>

We have frequently admonished litigants for "shotgun pleadings." Although the First Amended Complaint was improved, both complaints here nevertheless fall

<sup>&</sup>lt;sup>6</sup> We will excuse appellant's typographical error, whereby the complaint reincorporated all prior paragraphs into each count. This mistake did not appear in the original complaint and was represented to the court below, in response to the motion to dismiss, as a typographical error.

within the category of "shotgun complaints." See, e.g., Strategic Income Fund, L.L.C. v. Spear, Leeds & Kellogg Corp., 305 F.3d 1293, 1295 (11th Cir. 2002) ("The typical shotgun complaint contains several counts, each one incorporating by reference the allegations of its predecessors, leading to a situation where most of the counts (i.e., all but the first) contain irrelevant factual allegations and legal conclusions."); Johnson Enters. of Jacksonville, Inc. v. FPL Group, Inc., 162 F.3d 1290, 1333 (11th Cir. 1998) ("These types of cases invariably begin with a long list of general allegations, most of which are immaterial to most of the claims for relief. The general allegations are incorporated by reference into each count of the complaint . . . . "); Cesnik v. Edgewood Baptist Church, 88 F.3d 902, 905 (11th Cir. 1996) ("[The complaint] was framed in complete disregard of the principle that separate, discrete causes of action should be plead [sic] in separate counts. Count one, for example, which is labeled 'Wrongful Placement and Adoption,' purports to plead at least nine discrete theories of recovery." (internal citation omitted)).

When faced with a shotgun complaint, we have encouraged defendants to make motions for more definite statements or courts to demand repleader—and not, as the case were, to dismiss a complaint with prejudice. <u>See Anderson v. Dist. Bd.</u> <u>of Trs. of Cent. Fla. Cmty. Coll.</u>, 77 F.3d 364, 367 & n.5 (11th Cir. 1996) (stating that defendant is "expected" to move the court for a more definite statement in

response to a shotgun pleading and, failing that, the district court should sua sponte strike a shotgun complaint and require plaintiff to make a more definite statement); see also Davis v. Coca-Cola Bottling Co. Consol., 516 F.3d 955, 983-984 (11th Cir. 2008) (describing same procedure). But, that said, the Court has suggested at least once that if a party fails to heed the court's direction to revise a shotgun complaint, under some circumstances a dismissal and sanctions might be appropriate. See Byrne v. Nezhat, 261 F.3d 1075, 1133 (11th Cir. 2001) ("Implicit in such instruction is the notion that if the plaintiff fails to comply with the court's order—by filing a repleader with the same deficiency—the court should strike his pleading or, depending on the circumstances, dismiss his case and consider the imposition of monetary sanctions."). We are not, however, convinced that the instant case was one with respect to which a dismissal with prejudice was appropriate under the circumstances.

Moreover, a complaint—so long as it is minimally sufficient to put a defendant on notice of the claims against him—will not fail for mere surplusage. <u>See United States ex rel Garst v. Lockheed-Martin Corp.</u>, 328 F.3d 374, 378 (7th Cir. 2003) ("Surplusage can and should be ignored. Instead of insisting that the parties perfect their pleadings, a judge should bypass the dross and get on with the case."); <u>Davis v. Ruby Foods, Inc.</u>, 269 F.3d 818, 820 (7th Cir. 2001) (holding that

"it is an abuse of discretion . . . to dismiss a complaint merely because of the presence of superfluous matter"). We have recognized that "[p]leading facts not necessary to state a claim is not grounds for dismissal of a complaint . . . ." <u>Athens Newspapers v. Jefferson Standard Life Ins. Co.</u>, 729 F.2d 1412, 1417 (11th Cir. 1984). In other words, "[a] complaint is sufficient if the plaintiff is entitled to relief under any legal theory." <u>Thompson v. Allstate Ins. Co.</u>, 476 F.2d 746, 749 (5th Cir. 1973).<sup>7</sup> We will, therefore, overlook some of the extraneous and repetitious statements in appellant's First Amended Complaint, so long as the complaint is minimally sufficient to satisfy the notice pleading standards of the Federal Rules.

Even if we are not convinced that this was an appropriate case for the district court to dismiss the entire complaint for procedural errors alone, we are constrained in the form of relief we can afford appellant by her own failure here to seek leave to amend her complaint before the district court. Under our precedent, the district court was not obligated <u>sua sponte</u> to provide appellant with an opportunity to amend her complaint prior to dismissing it with prejudice. <u>See Wagner v. Daewoo</u> <u>Heavy Inds. Am. Corp.</u>, 314 F.3d 541, 542 (11th Cir. 2002) (en banc) ("A district court is not required to grant a plaintiff leave to amend his complaint <u>sua sponte</u>

<sup>&</sup>lt;sup>7</sup> In <u>Bonner v. City of Prichard</u>, 661 F.2d 1206, 1209 (11th Cir. 1981) (en banc), this Court adopted as binding precedent all of the decisions of the former Fifth Circuit handed down prior to the close of business on September 30, 1981.

when the plaintiff, who is represented by counsel, never filed a motion to amend nor requested leave to amend before the district court."); see also Long v. Satz, 181 F.3d 1275, 1279-80 (1999) (requiring plaintiff to make by separate motion, setting forth the substance of proposed amendments, a request for leave to amend a complaint); Fed. R. Civ. P. 7(b)(1)(A) ("A request for a court order must be made by motion. The motion must: (A) be in writing unless made during a hearing or trial").<sup>8</sup> Therefore, if we are to conclude that there was an abuse of discretion by the district court in dismissing any part of First Amended Complaint, we must find that appellant sufficiently remedied the procedural errors in the amended complaint such that it was unreasonable for the district court to dismiss that count. Although this is indeed a close case, we find that the district court abused its discretion when it dismissed Count I, the strict products liability claim, and Count IV, the breach of implied warranty of merchantability claim. With respect to Count II, we conclude that appellant failed to take full advantage of the opportunity afforded her by the district court when it gave appellant an opportunity to cure the original complaint's

<sup>&</sup>lt;sup>8</sup> The closest appellant came to making such a request was a request that her breach of express warranty claim (Count VII) be dismissed without prejudice, after conceding in her response to the motion to dismiss that the count failed to state a claim. Response to Motion to Dismiss, Docket No. 37, at 7.

procedural deficiencies, with specific instructions as to how to cure the complaint's errors.

#### B. <u>Count I: Strict Products Liability</u>

For the following reasons, we conclude that Count I, which was pled against all defendants, articulated a viable claim and minimally satisfied the district court's instructions in the context of a strict liability claim.

#### 1. Procedural Sufficiency of Count I

In its November 2006 order, the district court instructed appellant to replead her claims because each defendant was "entitled to a Complaint containing specific allegations of their alleged wrongdoing separated into individual counts." Although the court and the defendants believed that instruction to mean that appellant should break down each individual count as to each individual defendant—i.e., "Count I, design defect against Johnson & Johnson"—it was not necessarily clear that its instruction to appellant would have been violated by the First Amended Complaint's grouping of its strict products liability claim against all companies in the chain of distribution. <u>Samuel Friedland Family Enters. v.</u> <u>Amoroso</u>, 630 So. 2d 1067, 1068 (Fla. 1994) ("The underlying basis for the doctrine of strict liability is that those entities within a product's distributive chain who profit from the sale or distribution of [the product] to the public, rather than an innocent person injured by it, should bear the financial burden of even an undetectable product defect." (internal quotations and citations omitted; bracket in original)); <u>see also</u> Restatement (Third) of Torts §1 (1998) ("One engaged in the business of selling or otherwise distributing products who sells or distributes a defective product is subject to liability for harm to persons or property caused by the defect."). Because the First Amended Complaint appropriately indicated that each defendant could be liable, having participated in distributing, manufacturing, and retailing this product, we believe appellant sufficiently satisfied the court's instruction as to Count I.

The very nature of a products liability action—where the cause or source of the defect is not obvious to the consumer—would make it difficult for an appellant to pinpoint a specific source of defect against one entity along the chain of distribution prior to discovery. Moreover, the Federal Rules permit pleading in the alternative, even within one single count. See also Fed. R. Civ. P. 8(d)(2) ("A party may set out 2 or more statements of a claim or defense alternatively or hypothetically, either in a single count or defense or in separate ones. If a party makes alternative statements, the pleading is sufficient if any one of them is sufficient."). And although the district court had discretion to order "each claim founded on a separate transaction or occurrence . . . stated in a separate count,"

Fed. R. Civ. P. 10(b), appellant was not in a position to know what entity along the chain of distribution would have been responsible for the defect—or even to know with specificity before discovery what was the likely source of the defect. Moreover, under Florida law, we do not believe such precision would be required. <u>See Samuel Friedland Family Enters.</u>, 630 So. 2d at 1068 (describing liability running with the chain of profit).

Similarly, it would be difficult at such an early stage in the litigation for a plaintiff to know whether a defect was due to a product's design or manufacture, despite the district court's insistence that appellant specifically plead the source of the defect and not commingle available theories of strict liability recovery. We are not convinced that Florida law applies a rigid distinction among the various theories of recovery available to plaintiffs under strict products liability such that a plaintiff would be required to expressly plead "design defect" versus "manufacturing defect" at the complaint stage. See, e.g., Clark v. Boeing Co., 395 So. 2d 1226, 1229 (Fla. 3d DCA 1981) ("In order to establish strict liability, appellants must allege and prove the manufacturer's relationship to the product in question, the defect, the unreasonably dangerous condition of the product, and the existence of a proximate causal connection between the condition and the user's injuries or damage."); West v. Caterpillar Tractor Co., Inc. 336 So. 2d 80, 87 (Fla.

1976) (same) (adopting §402A of the Restatement (Second) of Torts for strict products liability in tort); Restatement (Second) of Torts §402A (1965) (establishing elements of strict liability recovery but not differentiating between design defect and manufacturing defect).<sup>9</sup> It is difficult for a plaintiff at this stage in the litigation to know the source of the defect that was responsible for the harm caused: whether there was a surprising manufacturing problem, a systemic issue with a product in its design, or a failure on the part of the manufacturer to warn doctors that particular uses might pose an unreasonable risk of harm.

Incidentally, we observe that Florida's Third District Court of Appeals in <u>Bergalia v. Ownes-Corning Fiberglass Corp.</u>, 606 So. 2d 1213, 1214 (Fla. 3d DCA 1992), reversed the trial court's dismissal of a strict liability count that similarly relied on multiple theories of strict liability—design defect, manufacturing defect,

<sup>&</sup>lt;sup>9</sup> Comment (k) to the Restatement (Second) of Torts §402A, adopted by the Supreme Court of Florida in <u>West</u>, specifically contemplates strict liability for drug manufacturers: "The seller of such products, <u>again with the qualification that they are properly</u> <u>prepared and marketed, and proper warning is given</u>, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk." Restatement (Second) of Torts §402A cmt. k (emphasis added). We note that the Restatement does not separately define the elements for design defect, manufacturing defect, and failure to warn therein, but at least manufacturing defect and failure to warn are contemplated by Comment (k) and encompassed under the umbrella strict products liability cause of action. Florida law also recognizes design defect in some circumstances – whereas other jurisdictions and Comment (k) do not. <u>See Adams v. G.D. Searle & Co.</u>, 576 So. 2d 728, 732-33 (Fla. 2d DCA 1991) (interpreting Comment (k) as an affirmative defense and permitting design defect claims).

and failure to warn—in a single strict liability count.<sup>10</sup> The lower court in <u>Bergalia</u> had dismissed the wordy count because it had appeared to state a claim for

<sup>10</sup> The <u>Bergalia</u> complaint read in pertinent part as follows:

COUNT II-STRICT LIABILITY

15. The allegations contained in paragraphs 1 through 9 are realleged.

16. Each of the Defendants' asbestos products contained latent characteristics or latent functional manufacturing and design defects at the time they were manufactured and at the time Plaintiff was exposed to the asbestos fibers from those products which each of the Defendants knew or, in the exercise of reasonable care should have known, would cause injuries to persons such as the Plaintiff.

17. At the time of Plaintiff's exposure, the Defendants' asbestos products were being used in the manner intended and without substantial change affecting their condition, but they contained latent characteristics or latent manufacturing design defects which made them unreasonably dangerous and unfit for their intended use, in that:

a. the products were designed to contain asbestos, a substance hazardous and highly harmful to the Plaintiff's body;

b. the Defendants failed to adequately test their products to determine the harmful effects caused by inhalation of asbestos fibers;

c. the products did not contain a sufficient warning to advise Plaintiff that the asbestos and asbestos-containing products were extremely harmful to his health and the health of his family members.

18. Plaintiff's illness was a direct and proximate result of the products' defects and Plaintiff has suffered the damages described.

WHEREFORE, Plaintiff demands compensatory damages, punitive damages, and trial by jury of all issues so triable in this cause.

Bergalia, 606 So. 2d at 1214 (quoting plaintiff's complaint).

negligence, and not strict liability. <u>Id.</u> The district court of appeals reversed and found that the "negligence-type allegation" was "mere surplusage," without even addressing itself to the fact that multiple theories of strict liability were pled within a single count.

For the foregoing reasons, we conclude that the First Amended Complaint satisfied the district court's instructions with respect to Count I. We conclude that the district court abused its discretion in dismissing the complaint with prejudice on account of procedural deficiencies.

## 2. Substantive Sufficiency of Count I

In the seminal <u>West</u> case, the Supreme Court of Florida adopted strict liability for manufacturers and sellers whose products reach a consumer in an unreasonably dangerous condition and thereafter cause injury. <u>West</u>, 336 So. 2d at 86-87. "In order to hold a manufacturer liable on the theory of strict liability in tort, the suer must establish the manufacturer's relationship to the product in question, the defect and unreasonably dangerous condition of the product, and the existence of the proximate causal connection between such condition and the user's injuries or damages." <u>Id.</u> at 87; <u>see also Clark</u>, 395 So. 2d at 1229; <u>see also Cintron</u> <u>v. Osmose Wood Preserving, Inc.</u>, 681 So.2d 859, 861 (Fla. 5th DCA 1996) (holding that "a cause of action on the theory of strict liability may be properly pled by alleging: (1) the manufacturer's relationship to the product in question, (2) the unreasonably dangerous condition of the product, and (3) the existence of a proximate causal connection between the condition of the product and the plaintiff's injury."). In other words, there are three elements to a strict liability products claim under Florida law: (1) a relationship between the defendant and the product; (2) a defect which caused the product to be unreasonably dangerous; (3) causation between the defect and the harm suffered by the user.

Although the doctrine of strict liability does not seek to make companies insurers of their products, it does impose liability when a product is not "reasonably safe for its intended use as manufactured and designed when it left the plant of the manufacturer." <u>Clark</u>, 395 So. 2d at 1229. The <u>West</u> court also recognized that consumer misuse and contributory negligence beyond merely failing to discover the defect itself could raise a valid defense to strict liability but would not bar such an action. <u>West</u>, 336 So. 2d at 90. Florida courts apply the basic elements of a strict liability claim with equal force to medical device and prescription drug manufacturers, and in recognition of the dangerous nature of those products, permit those defendants to raise a risk-benefit analysis as an affirmative defense to liability. <u>See Adams v. G.D. Searle & Co.</u>, 576 So. 2d 728, 732-33 (Fla. 2d DCA 1991) (permitting seller of product to raise affirmative

defense of product's risk-benefit analysis under a design defect theory of liability for a medical product).

Here, admittedly, appellant's complaint weaves multiple defect theories under the rubric of strict liability, but we do not find this fatal to having stated a valid cause of action. Although it takes some piecing together, appellant established minimally sufficient factual allegations to support her claim for strict products liability under either a manufacturing or design defect avenue to liability for these defendant manufacturers and sellers of the Duragesic patch.

First, the complaint alleged that each defendant participated in the "business of designing, creating, manufacturing, testing, labeling, packaging, supplying, marketing, selling, advertising, warning and otherwise distributing and placing in the stream of commerce" the patches, thus alleging (albeit very broadly) that each defendant had a relationship to the product at issue and derived revenue from its sale. First Amended Complaint ¶46, at 13. This minimally satisfied the required relationship element of the strict liability test.

Second, although the complaint alleges in a conclusory fashion that the patch reached Beal in an unreasonably dangerous condition, it nevertheless proceeds to suggest several possible defects existing at the time of Beal's use of the Duragesic patch. The amended complaint alleges that the product "[r]elased its narcotic

medication into [Beal's] skin, body, and circulatory system at a dangerous rate" or, in other words, "at a rate faster than its advertised rate of 75 mcg/hour." Id. ¶55(c)-(d), at 16. More specifically, the complaint alleges that the patch suffered from a malfunction in its "protective liner and functional layers," which "leaked and failed to deliver fentanyl from the drug reservoirs at the declared constant amount per unit of time of 75 mcg/hour." Id. ¶55(e), at 16.<sup>11</sup> In short, appellant identified the source of the defect: a leak in the protective lining and functional layers, which caused the product to dispense its medication at a dangerous and lethal rate. Whether this leak was the result of a manufacturing error along the assembly line or because of a faulty design in the patch itself would be difficult for a consumer to know prior to discovery. But these allegations are sufficient to allow defendants to frame a responsive pleading directed at a defect in either the design or manufacturing of the patch's layers that caused a leak resulting in the delivery of a fatal dose of fentanyl. The complaint, therefore, alleged a defect that made the patch unreasonably dangerous, the second element of strict liability.

<sup>&</sup>lt;sup>11</sup> Elsewhere in the First Amended Complaint, appellant suggested other defects that were known to the defendants at the time of Beal's death, which also provide a sufficient factual basis to suggest the unreasonably dangerous condition of the product. These defects included "foldovers in the backing of the patch system; gel in the seal; seal breaches; corners of the patch system cut off; holes in the drug reservoir; slits in the patch's pouch and system; air bubbles in the adhesive layers of the system; no gel in the system; and lack of adhesions in the patch system." First Amended Complaint ¶24, at 7.

Lastly, the complaint alleged a sufficient causal connection between use of the patch and Beal's death. It establishes that Beal died within one day of his use of the patch as a result of fentanyl toxicity. Moreover, any apparent misuse of the product by Beal or by his prescribing physician is relevant only as an affirmative defense under Florida law, and therefore need not be affirmatively pled in the amended complaint. We therefore conclude that the complaint, in Count I, set forth sufficient factual allegations to support a claim for strict products liability under either a design or manufacturing defect theory of recovery.<sup>12</sup>

We are not convinced, however, that Appellant sufficiently pled any facts to suggest that the defendant companies are responsible under a theory of strict liability for failing to adequately warn of potential harms. Florida law applies the learned intermediary doctrine, whereby the duty to warn flows from the drug manufacturer to the physician, and not the ultimate consumer. <u>See Felix v.</u> <u>Hoffmann-LaRoche, Inc.</u>, 540 So. 2d 102, 104 (Fla. 1989) ("At the outset, it is clear that the manufacturer's duty to warn of [the drug's] dangerous side effects was directed to the physician rather than the patient."). So long as a drug's

<sup>&</sup>lt;sup>12</sup> The district court cited the failure to allege an alternative design and the feasibility of this design as part of the substantive failures of the amended complaint. In supplemental authority, appellant proffered a recent Florida District Court of Appeals decision where a divided panel held that "there is no requirement of an alternative design in a design defect claim." Liggett Group, Inc. v. Davis, 973 So.2d 467, 477 (Fla. 4th DCA 2007).

warning to the prescribing physician is adequate, a manufacturer will not be strictly liable for failure to warn when a doctor prescribes a particular drug or fails to inform his patient of certain risks associated with the medication, such as, in this case, post-operative administration of the Duragesic patch. Id. at 105 ("Insofar as the liability of the manufacturer is concerned, it makes no difference that the [plaintiff] testified that [her physician] did not warn her of the danger of taking [drug] while pregnant. While this would present a factual issue in a claim against the doctor, the drug manufacturer could not be penalized for the failure of the doctor to impart knowledge concerning the dangers of the drug of which the doctor had been warned and was aware."). In only one conclusory sentence, the complaint pleads the inadequacy of the warnings to doctors: "The defective patches were not accompanied by adequate instructions and/or warnings to fully apprise the prescribing physicians . . . of the full nature or extent of the risks and side effects associated with its use." First Amended Complaint ¶55(k), at 16. Nowhere does the complaint recite the contents of the warning label or the information available to Beal's physician or otherwise describe the manner in which the warning was inadequate. Count I only asserts that the warning was insufficient because it failed to warn of various dangers of the use of this opiate, without explaining either the

information available to Beal's physician at the time of the administration of the drug or how the contents of the label were inadequate.

In sum, then, we find that the First Amended Complaint's procedural deficiencies did not warrant dismissal of Count I with prejudice in light of the nature of strict liability recovery and the particular instructions of the district court. With respect to substantive deficiencies, we conclude that Count I minimally sets forth the requisite factual basis to establish a design or manufacturing defect that would give rise to strict liability against these defendants and permits appellant to survive defendants' motion to dismiss, as to Count I.<sup>13</sup>

## C. <u>Count II: Negligence</u>

Whereas the nature of strict products liability actions saved Count I of appellant's amended complaint in this instance, it does not preserve appellant's negligence claim in the face of the district court's instructions to plead individual claims against individual defendants. In other words, because a negligence action requires the plaintiff to establish the duty, breach, and causation elements as to each defendant, appellant's complaint, which pleads negligence in Count II against three defendants collectively, failed to follow the district court's instruction. Per

<sup>&</sup>lt;sup>13</sup> However, we affirm the district court to the extent that it dismissed with prejudice a strict liability claim for failure to warn.

the district court's instruction, appellant should have explained each defendant's individual duty and breach based on its role in the creation of the patch. Without deciding, therefore, whether Count II fails substantively as well, we are unable to say that the district court abused its discretion when it dismissed Count II on procedural grounds alone, especially in light of appellant's failure even to move for leave to amend.

### D. <u>Count IV: Breach of Warranty of Merchantability</u>

It does not appear that the district court found substantive error in appellant's claim against defendant Walgreen, the seller, for breach of the implied warranty of merchantability, but only dismissed this claim for procedural errors because it was commingled with the claim for breach of fitness for a particular purpose under Count IV. Appellant's argument on appeal appears to concede that the First Amended Complaint commingled a claim for breach of the implied warranty of merchantability and breach of the implied warranty of fitness for a particular purpose in Count IV, the "Breach of Implied Warranty Walgreen" claim. Appellant's brief seeks reinstatement of the "warranty of merchantability theory" under Count IV, as opposed to suggesting that the entire Count was sufficiently pled.

However, we do not find that Count IV violated the district court's instruction on commingling.<sup>14</sup> It was pled only against one defendant and only alleges a factual basis sufficient to make out a claim for breach of the implied warranty of merchantability, and not for an implied warranty of fitness for a particular purpose. Under Florida law, a seller must have "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" in order to create an implied warranty for a particular purpose. Fla. Stat. Ann. § 672.315 (West 2006). Nowhere in Count IV did appellant allege facts to suggest that the seller, Walgreen, was made aware of Beal's particular use for the product, nor that Beal relied upon the buyer's expertise to purchase the Duragesic patch. Although language in Count IV refers to the product as not being "fit for a particular purpose," having failed to plead other elements of that warranty claim, we will ignore this language as surplusage. See United States ex rel Garst, 328 F.3d at 378; Athens Newspapers, 729 F.2d at 1417. It was, therefore, an abuse of discretion for the district court to dismiss the count for being commingled with another claim when the count fails to set forth any elements of that purported additional

<sup>&</sup>lt;sup>14</sup> We are excusing the typographical error that otherwise would cause express commingling of all the counts. <u>See supra</u> note 6.

commingled claim. Because the district court did not identify any substantive deficiencies as to the breach of the implied warranty of merchantability claim as to defendant Walgreen, we conclude that Count IV was properly pled.

#### IV. CONCLUSION

In short, we conclude that the district court was within its discretion to dismiss Count II of the First Amended Complaint but that Counts I and IV were minimally sufficient, both in form and substance. However, the only remaining counts on which discovery may be had and which will go to summary judgment or trial will be whether these defendants should be held strictly liable under either a design defect or manufacturing defect theory for Beal's death and whether Walgreen breached an implied warranty of merchantability when it sold the Duragesic patch to Beal. We expect that after discovery appellant will have an opportunity to better identify whether the purported defect at issue was a result of design or manufacturing error or both.

We affirm<sup>15</sup> in part, reverse in part, and remand this action to the district court for proceedings consistent with this opinion.

## AFFIRMED IN PART, REVERSED IN PART, and REMANDED.

<sup>&</sup>lt;sup>15</sup> As noted above, this opinion is an appendix to our simultaneously issued published opinion affirming the district court's denial of appellant's motion to remand to state court.